Robert Francis QC

Press Statement

Today I publish the report of this Inquiry following my consideration of the evidence of over 250 witnesses and over a million pages of documentary material. It builds on my earlier report, published in February 2010 after the earlier independent inquiry on the failings in the Mid Staffordshire NHS Foundation Trust between 2005 and 2009. I recommend that those seeking a full understanding of all the issues read both reports.

This is a story of appalling and unnecessary suffering of hundreds of people. They were failed by a system which ignored the warning signs and put corporate self interest and cost control ahead of patients and their safety. I have today made 290 recommendations designed to change this culture and make sure that patients come first.

We need a patient centred culture, no tolerance of non compliance with fundamental standards, openness and transparency, candour to patients, strong cultural leadership and caring, compassionate nursing, and useful and accurate information about services.

The evidence at both inquiries disclosed that patients were let down by the Mid Staffordshire NHS Foundation Trust. There was a lack of care, compassion, humanity and leadership. The most basic standards of care were not observed, and fundamental rights to dignity were not respected. Elderly and vulnerable patients were left unwashed, unfed and without fluids. They were deprived of dignity and respect. Some patients had to relieve themselves in their beds when they offered no help to get to the bathroom. Some were left in excrement stained sheets and beds. They had to endure filthy conditions in their wards. There were incidents of callous treatment by ward staff. Patients who could not eat or drink without help did not receive it. Medicines were prescribed but not given. The accident and emergency department as well as some wards had insufficient staff to deliver safe and effective care. Patients were discharged without proper regard for their welfare.

The many experiences like this were truly shocking to hear. Many will find it difficult to believe that all this could occur in an NHS hospital. I want to pay tribute to the many patients and those close to them who bravely and with

great dignity gave evidence to me at the two inquiries. It is their efforts which have brought these shocking facts to light. It is important for them, and all others who have suffered as they have that the necessary changes are made to protect patients and to provide the proper and fundamental standards of care to which we are all entitled.

What brought about this awful state of affairs? The Trust Board was weak. It did not listen sufficiently to its patients and staff or ensure the correction of deficiencies brought to the Trust's attention. It did not tackle the tolerance of poor standards and the disengagement of senior clinical staff from managerial and leadership responsibilities. These failures were in part due to a focus on reaching targets, achieving financial balance and seeking foundation trust status at the cost of delivering acceptable standards of care.

The purpose of this inquiry was to work out why these problems many of which should have been evident over a period of years, were not discovered earlier. Regrettably there was a failure of the NHS system at every level to detect and take the action patients and the public were entitled to expect.

- The patient voice was not heard or listened to, either by the Trust Board or local organisations which were meant to represent their interests. Complaints were made but often nothing effective was done about them.

- The local medical community did not raise concerns until it was too late.

- Local scrutiny groups were not equipped to understand or represent patient concerns or to challenge reassuring statements issued by the Trust.

- The Primary Care Trusts which were under a duty to arrange for the provision of safe and effective care were not set up for and did not effectively ensure the quality of the health services they were buying; they did not have the tools to do the job properly

- The Strategic Health Authority was the regional representatives of the NHS and the Department of Health. It did not put patient safety and wellbeing at the forefront of its work. It defended trusts rather than holding them to account on behalf of patients. It was uncritical in its support of Foundation trust status for the Trust. It preferred to explain

away concerns such as those about high mortality rates rather than root out matters which would concern any patient.

- Monitor's duty was to ensure that trusts were fit to be granted the independence of Foundation Trust status. It focussed on corporate governance and financial control without properly considering whether there were issues of patient safety and poor care.

- The Department of Health did not ensure that ministers were given the full picture when advising that the Trust's application for Foundation Trust status should be supported. It was remote from the reality of the service at the front line.

- The Healthcare Commission was required to assess trusts against standards which did not adequately test the quality of care being provided to patients, but it was its painstaking investigation by a team of skilled inspectors that eventually brought the truth to light. Even then there was a reluctance by those who had the power to do so to intervene urgently to protect patients.

- Other organisations, including healthcare professional regulators, training and professional representative organisations failed to uncover the lack of professionalism and take action to protect patients.

At every level there was a failure to communicate known concerns adequately to others, and to take sufficient action to protect patients' safety and wellbeing from the risks arising from those concerns. In short the trust that the public should be able to place in the NHS was betrayed.

What caused such a widespread failure of the system? This is not something which can be blamed simplistically on one policy or another, or on failings on the part of one or even a group of individuals. There was an institutional culture in which the business of the system was put ahead of the priority that should have been given to the protection of patients and the maintenance of public trust in the service. It was a culture which too often did not consider properly the impact on patients of actions being taken, and the implications for patients of concerns that were raised. It was a culture which trumpeted successes and said little about failings. Standards and methods of ensuring compliance were not focussed on the effect of service deficiencies on patients There was a tolerance of poor standards and the consequent risk to patients. Agencies frequently failed to share their knowledge with each other.

Assumptions were continually made that important functions were being performed satisfactorily by others. The dangers of the loss of corporate memory from major reorganisations were inadequately addressed and during the reorganisation of PCTs and SHAs there was a loss of focus upon the care patients received.

The NHS is full of dedicated, skilled people committed to providing the best possible care to their patients. There is much to be proud of about what they do for us. However the service so valued in this country and respected internationally is in danger of losing public trust unless all who work in it take personal and collective responsibility to root out poor practice wherever it is to be found.

What do we need?

Conventionally, some might say depressingly, when a disaster has occurred in the NHS the usual approach has been to blame and sack individuals or to propose major reorganisations. What has been found to be wrong here cannot be cured by finding scapegoats, and/ or recommending major reorganisations yet again

What is required now is a real change in culture, a refocusing and recommitment of all who work in the NHS – from top to bottom of the system - on putting the patient first. We need a common patient centred culture which produces at the very least the fundamental standards of care to which we are all entitled, at the same time as celebrating and supporting the provision of excellence in healthcare.

We need common values, shared by all, putting patients and their safety first; we need, a commitment by all to serve and protect patients and to support each other in that endeavour, and to make sure that the many committed and caring professionals in the NHS are empowered to root out any poor practice around them. These values need to be the principal message of the NHS constitution, to which all staff must commit themselves.

How is this to be done?

The NHS is a complex and frequently re-organised system trying to maintain its service against a backdrop of increasing demands and challenging financial expectations. The last thing required is a set of proposals from me requiring more radical reorganisation. So my recommendations are intended above all to support all in the service to make patient centred values and

standards real, but also to bring teeth to the task of changing behaviours where required. Essentially I think five things are needed:

- First, a structure of clearly understood fundamental standards and measures of compliance, accepted and embraced by the public and healthcare professionals, with rigorous and clear means of enforcement: we need a list of standards, about patient safety, the effectiveness of treatment, and basic care - the requirements we will all agree should be in place to permit any hospital service to continue. These standards should be defined by what patients and the public want and are entitled to, and what healthcare professionals agree can be delivered. Non compliance with these fundamental standards cannot be tolerated. Any organisation unable consistently to comply should be prevented from continuing a service which exposes patients to risk. To cause death or serious harm to a patient by non-compliance with fundamental standards should be a criminal offence. Standard procedures, guidance and assessment tools designed to enable organisations and individuals to comply with fundamental standards in different clinical settings should be produced by the National Institute of Clinical Excellence (NICE), with the help of relevant professional and patient organisations. These should include guidance on staffing. Individuals should be supported to report non compliance or matters which might prevent compliance to their organisations. They should be protected when they do this.

 Fundamental standards must be policed by the Care Quality Commission. It is this inquiry's firm conclusion that physical inspection by well qualified, trained and experienced hospital inspectors is the most effective means of monitoring compliance with standards in hospitals. Regulation would also be more effective if compliance with fundamental standards and requirements for clinical and corporate governance and finance control, were regulated by one organisation. The CQC should regulate all these matters together rather than responsibility being divided between CQC and Monitor. The CQC would also be expected to intervene where necessary to protect patients from non-compliance with the fundamental standards.

In all walks of life the buyer wants to ensure that he gets what he pays for. Health should be no different. Therefore commissioners of healthcare services must be required to develop and require compliance with other standards – which I have called enhanced quality standards - of quality, effectiveness and other requirements over and above the fundamental standards. As the buyer of these services on our behalf commissioners must ensure that these enhanced standards are delivered by their providers. In this way the role of the regulator and commissioners responsibility would be simplified and clarified.

- Secondly, openness, transparency and candour throughout the system: A common culture of serving and protecting patients and of rooting out poor practice will not spread throughout the system without insisting on openness, transparency and candour everywhere in it. A duty of candour should be imposed and underpinned by Statute and the deliberate obstruction of this duty should be made a criminal offence.
 - Openness means enabling concerns and complaints to be raised freely and fearlessly, and questions to be answered fully and truthfully;
 - Transparency means making accurate and useful information about performance and outcomes available to staff, patients, the public and regulators.
 - Candour means informing any patient who has or may have been avoidably harmed by a healthcare service of that fact and a remedy offered where appropriate, regardless of whether a complaint has been made or a question asked about it.

Every provider trust must be under an obligation to tell the truth to any patient who has or may have been harmed by their care. It is not in my view sufficient to support this need by a contractual duty in commissioning arrangements. It requires a duty to patients, recognised in statute, to be truthful to them. It requires staff to be obliged by statute to make their employers aware of incidents in which harm has or may have been caused to patients so they can take the necessary action. The deliberate obstruction of the performance of these duties and the deliberate deception of patients in this regard should be criminal offences. So called “gagging clauses” which might prevent a concerned employee or ex employee raising honestly held concerns

about patient safety should be banned. Trusts must be open and honest with regulators. It should be an offence deliberately to give them misleading information. Information provided to the public about performance should be required to be balanced, truthful and not misleading by omission. Quality accounts should be independently audited. The CQC should be responsible for policing these obligations.

- Thirdly, improved support for compassionate caring and committed nursing: proper standards of nursing care lie at the heart of what is required to protect patients when in hospital. The majority of nurses are compassionate, caring and committed. They should be given effective support and recognition, and be empowered to use these qualities to maintain standards. Entrants to the profession should be assessed for their aptitude to deliver and lead proper care, and their ability to commit themselves to the welfare of their patients. Training standards need to be created to ensure that qualified nurses are competent to deliver compassionate care to a consistent standard and their training must incorporate the need to experience hands-on patient care. Named clinicians should be responsible for the welfare and care of each patient in hospital.

 Healthcare support workers are a highly important but insufficiently valued part of the workforce: they provide most of the hands on care for elderly and vulnerable patients. They need the help of consistent training, and standards of performance. Patients are not currently adequately protected from those who are unfit to do this work. The time has come in for healthcare support workers to be regulated by a registration scheme enabling those who should not be entrusted with the care of patients to be prevented from being employed to do so. This needs to be supported by common training standards and a code of conduct. No-one should have hands-on care of patients unless properly trained and registered. Patients and the public are entitled to greater clarity about the status of those who provide direct physical care to them.

 Nursing needs a stronger voice. This can be achieved by strengthening nursing representation in organisational leadership, enhancing the links with their professional regulators, better appraisal, and encouraging strong nursing leadership at ward level. I would like to see more recognition of the extremely important role nursing plays in the care of

older patients by the creation of a new registered status as a registered older person's nurse. I would like their profession to consider how greater authority can be brought to their representative voice.

- Fourthly strong and patient centred healthcare leadership: leadership generally in the NHS is under challenge and needs more effective support. The necessary culture will only flourish if leaders reinforce it every day in every part of the service. A NHS leadership staff college could be created, offering all potential and current leaders the chance to share in a form of common training designed to equip them to exemplify and implement the common culture. They should be supported by a common code of ethics and conduct for all leaders and senior managers.

 The public are entitled to expect leaders to be held to account effectively when they have not applied the core values of the Constitution, or are otherwise shown to be unfit for the role. Currently leaders who are registered as doctors or nurses can be disciplined by a regulator for failing to protect patients. Other leaders cannot. A more level playing field would enhance leadership teamwork and increase the public's confidence in the NHS. It should be possible to disqualify those guilty of serious breach of the code of conduct or otherwise found unfit from eligibility for leadership posts. This will require a registration scheme and a requirement that only fit and proper persons are eligible to be directors of NHS organisations. While this regulatory function could be performed by an existing regulator, the need for a separate entity for this purpose should be kept under review.

- Finally, accurate, useful and relevant information: information is the lifeblood of an open transparent and candid culture. All professionals, individually and collectively, should be obliged to take part in the development, use and publication of more sophisticated measurements of the effectiveness of what they do, and of their compliance with fundamental standards. Patients, the public, employers, commissioners and regulators need access to accurate, comparable and timely information. Improvements are needed in the core information systems for the collection of data about patients, both to support their individual treatment and the accurate collation of information for statistical purposes. Difficulties in achieving this are no

excuse for inaction. The Information Centre for Health and Social Care has an important role to play in this field. Boards must be accountable for the presentation to the public of balanced and candid information about their trusts' compliance with fundamental standards. It should be a criminal offence to be a party to a wilful or reckless false statement as to compliance with safety or fundamental standards.

Many of my recommendations will require development in detail to be implemented. The suffering undergone by patients and those close to them in Stafford demands that the lessons to be learned are not considered for a day or two and then forgotten. Government and the Department of Health have an important role to play in changing the culture, but this does not mean everyone else in the system can sit back and wait to be told what to do. Every single person and organisation within the NHS, and not only those whose actions are described in this report, need to reflect from today on what needs to be done differently in future. All have a responsibility to consider what is exposed by my two inquiries, and to consider how to apply the lessons themselves, individually and collectively. I have recommended that every organisation should report publically on a regular basis on whether they have accepted my recommendations and what they are doing to implement them, and that the House of Commons Health Select Committee should be invited to review regularly the progress being made by organisations which are accountable to Parliament.

My recommendations represent not the end but the beginning of a journey towards a healthier culture in the NHS in which good practice in one place is not considered to be a reason for ignoring poor practice somewhere else; where personal responsibility is not thought to be satisfied by a belief that someone else is taking care of it; where protecting and serving patients is the conscious purpose of everything everyone thinks about day in day out. Patients are entitled to be the first and foremost consideration of the system and all those who work in it. I very much hope that this report and its recommendations will help to bring this about.

6 February 2013

THE MID STAFFORDSHIRE
NHS FOUNDATION TRUST
PUBLIC INQUIRY

Chaired by Robert Francis QC

Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry

Executive summary

HC 947

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February 2013

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Presented to Parliament pursuant to Section 26 of the Inquiries Act 2005

Ordered by the House of Commons to be printed on 6 February 2013

HC 947 London: The Stationery Office £30.00

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This publication is available for download at www.official-documents.gov.uk and from our website at www.midstaffspublicinquiry.com

ISBN: 9780102981476

Printed in the UK for The Stationery Office Limited

on behalf of the Controller of Her Majesty's Stationery Office

ID 2535334 01/13

Printed on paper containing 75% recycled fibre content minimum.

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Letter to the Secretary of State

Mid Staffordshire NHS Foundation Trust Public Inquiry
Skipton House
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80 London Road
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SE1 6LH

The Rt Hon Jeremy Hunt MP
Secretary of State for Health
Richmond House
79 Whitehall
London
SW1A 2NS

5 February 2013

Dear Secretary of State

Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry

As you know, I was appointed by your predecessor to chair a public inquiry under the Inquiries Act 2005 into the serious failings at the Mid Staffordshire NHS Foundation Trust. Under the Terms of Reference of the Inquiry, I now submit to you the final report.

Building on the report of the first inquiry, the story it tells is first and foremost of appalling suffering of many patients. This was primarily caused by a serious failure on the part of a provider Trust Board. It did not listen sufficiently to its patients and staff or ensure the correction of deficiencies brought to the Trust's attention. Above all, it failed to tackle an insidious negative culture involving a tolerance of poor standards and a disengagement from managerial and leadership responsibilities. This failure was in part the consequence of allowing a focus on reaching national access targets, achieving financial balance and seeking foundation trust status to be at the cost of delivering acceptable standards of care.

The story would be bad enough if it ended there, but it did not. The NHS system includes many checks and balances which should have prevented serious systemic failure of this sort. There were and are a plethora of agencies, scrutiny groups, commissioners, regulators and professional bodies, all of whom might have been expected by patients and the public to detect and do something effective to remedy non-compliance with acceptable standards of care. For years that did not occur, and even

after the start of the Healthcare Commission investigation, conducted because of the realisation that there was serious cause for concern, patients were, in my view, left at risk with inadequate intervention until after the completion of that investigation a year later. In short, a system which ought to have picked up and dealt with a deficiency of this scale failed in its primary duty to protect patients and maintain confidence in the healthcare system.

The report has identified numerous warning signs which cumulatively, or in some cases singly, could and should have alerted the system to the problems developing at the Trust. That they did not has a number of causes, among them:

- A culture focused on doing the system's business – not that of the patients;
- An institutional culture which ascribed more weight to positive information about the service than to information capable of implying cause for concern;
- Standards and methods of measuring compliance which did not focus on the effect of a service on patients;
- Too great a degree of tolerance of poor standards and of risk to patients;
- A failure of communication between the many agencies to share their knowledge of concerns;
- Assumptions that monitoring, performance management or intervention was the responsibility of someone else;
- A failure to tackle challenges to the building up of a positive culture, in nursing in particular but also within the medical profession;
- A failure to appreciate until recently the risk of disruptive loss of corporate memory and focus resulting from repeated, multi-level reorganisation.

I have made a great many recommendations, no single one of which is on its own the solution to the many concerns identified. The essential aims of what I have suggested are to:

- Foster a common culture shared by all in the service of putting the patient first;
- Develop a set of fundamental standards, easily understood and accepted by patients, the public and healthcare staff, the breach of which should not be tolerated;
- Provide professionally endorsed and evidence-based means of compliance with these fundamental standards which can be understood and adopted by the staff who have to provide the service;
- Ensure openness, transparency and candour throughout the system about matters of concern;
- Ensure that the relentless focus of the healthcare regulator is on policing compliance with these standards;
- Make all those who provide care for patients – individuals and organisations – properly accountable for what they do and to ensure that the public is protected from those not fit to provide such a service;

- Provide for a proper degree of accountability for senior managers and leaders to place all with responsibility for protecting the interests of patients on a level playing field;
- Enhance the recruitment, education, training and support of all the key contributors to the provision of healthcare, but in particular those in nursing and leadership positions, to integrate the essential shared values of the common culture into everything they do;
- Develop and share ever improving means of measuring and understanding the performance of individual professionals, teams, units and provider organisations for the patients, the public, and all other stakeholders in the system.

In introducing the first report, I said that it should be patients – not numbers – which counted. That remains my view. The demands for financial control, corporate governance, commissioning and regulatory systems are understandable and in many cases necessary. But it is not the system itself which will ensure that the patient is put first day in and day out. Any system should be capable of caring and delivering an acceptable level of care to each patient treated, but this report shows that this cannot be assumed to be happening.

The extent of the failure of the system shown in this report suggests that a fundamental culture change is needed. This does not require a root and branch reorganisation – the system has had many of those – but it requires changes which can largely be implemented within the system that has now been created by the new reforms. I hope that the recommendations in this report can contribute to that end and put patients where they are entitled to be – the first and foremost consideration of the system and everyone who works in it.

Yours sincerely



Robert Francis QC
Inquiry Chairman

Introduction

Background

1 Between 2005 and 2008 conditions of appalling care were able to flourish in the main hospital serving the people of Stafford and its surrounding area. During this period this hospital was managed by a Board which succeeded in leading its Trust[1] (the Mid Staffordshire General Hospital NHS Trust) to foundation trust (FT) status. The Board was one which had largely replaced its predecessor because of concerns about the then NHS Trust's performance. In preparation for its application for FT status, the Trust had been scrutinised by the local Strategic Health Authority (SHA) and the Department of Health (DH). Monitor (the independent regulator of NHS foundation trusts) had subjected it to assessment. It appeared largely compliant with the then applicable standards regulated by the Healthcare Commission (HCC). It had been rated by the NHS Litigation Authority (NHSLA) for its risk management. Local scrutiny committees and public involvement groups detected no systemic failings. In the end, the truth was uncovered in part by attention being paid to the true implications of its mortality rates, but mainly because of the persistent complaints made by a very determined group of patients and those close to them. This group wanted to know why they and their loved ones had been failed so badly.

2 The NHS is a service of which the country can be justly proud, offering as it does universal access to free medical care, often of the highest order. It is a service staffed by thousands of dedicated and committed staff and managers who have been shocked by what they heard of the events surrounding the Trust. It is inconceivable to many of them that conditions of the type described by so many patients can have been allowed to exist let alone persist. Those responsible for the oversight of the service, from Ministers to senior civil servants to those in charge of regulatory and commissioning bodies, have been bewildered at how this could have happened without it being discovered sooner.

3 Healthcare is not an activity short of systems intended to maintain and improve standards, regulate the conduct of staff, and report and scrutinise performance. Continuous efforts have been made to refine and improve the way these work. Yet none of them, from local groups to the national regulators, from local councillors to the Secretary of State, appreciated the scale of the deficiencies at Stafford and, therefore, over a period of years did anything effective to stop them.

4 As has been frequently pointed out to the Inquiry, the primary responsibility for allowing standards at an acute hospital trust to become unacceptable must lie with its Board, and the

1 In the time period looked at by the Inquiry, Mid Staffordshire General Hospitals NHS Trust was awarded Foundation Trust status and changed its name to the Mid Staffordshire NHS Foundation Trust. Throughout this report the term 'the Trust' has been used to denote both Mid Staffordshire General Hospitals NHS Trust and Mid Staffordshire NHS Foundation Trust.

Trust's professional staff. The system is designed for directors to lead and manage the provision of services within its allocated budget but in accordance with required standards, and for professional staff, informed by their ethical standards and commitment, to serve and protect their patients. If every board succeeded in that challenging task, and if all professional staff complied at all times with the ethics of their professions, there would have been no need for the plethora of organisations with commissioning and performance management responsibilities. It is because of the fact that not all boards are capable of maintaining acceptable standards or improving services at the required pace, or applying effective stewardship to the resources entrusted to them that healthcare systems regulators and performance managers exist. It is because not all professionals do live up to the high standards expected of them that we have professional regulators. All such organisations have the responsibility to detect and redress deficiencies in local management and performance where these occur. It does not need a public inquiry to recognise that this elaborate system failed dramatically in the case of Stafford. As a result, it is clear that not just the Trust's Board but the system as a whole failed in its most essential duty – to protect patients from unacceptable risks of harm and from unacceptable, and in some cases inhumane, treatment that should never be tolerated in any hospital.

5 The enormity of what occurred at this Trust has been consistently acknowledged by both the previous and the present Governments.

6 When presenting the report of the HCC on the Trust to the House of Commons, the Secretary of State for Health, the Rt Hon Alan Johnson MP, said:

> *I apologise on behalf of the government and the NHS for the pain and anguish caused to so many patients and their families by the appalling standards of care at Stafford hospital, and for the failures highlighted in the report.*[2]

7 I was first commissioned in July 2009 by the then Secretary of State for Health, the Rt Hon Andy Burnham MP, to chair a non-statutory inquiry, the principal purpose of which was to give a voice to those who had suffered at Stafford and to consider what had gone wrong there.

8 In announcing the first inquiry, Mr Burnham said:

> *All of us who care passionately about the health service were appalled by the events at Mid Staffordshire, which are in stark contrast to the dedication and professionalism shown by NHS staff every day up and down the country.*

9 It was not within that inquiry's Terms of Reference to examine the involvement of the wider system in what went wrong. What I heard shocked me, and the descriptions of what had

2 Hansard, 18 March, 2009 Column 909

been endured shocked those who read about them in my report, published in February 2010. It was clear to me, as it had been to the victims who gave evidence to me, that there needed to be an investigation of the wider system to consider why these issues had not been detected earlier and to ensure that the necessary lessons were learned.

10 I recommended that such an inquiry be held, a recommendation which was accepted by Mr Burnham, who asked me to chair a further non-statutory inquiry. In announcing that inquiry Mr Burnham told the House of Commons:

> *Let me be clear: the care provided was totally unacceptable and a fundamental breach of the values of the NHS.*[3]

11 He repeated the apology previously given by the Prime Minister:

> *Last year, the Prime Minister apologised to the people of Staffordshire. On behalf of the Government and the NHS, I repeat that apology again today. They were badly let down. I pay tribute to the people who had the courage to come forward and tell their stories and to expose the failures of the past, in order that they could protect others in the future.*[4]

12 Following the general election, Mr Burnham's successor, the Rt Hon Andrew Lansley CBE MP, the first Secretary of State for Health of the Coalition Government, confirmed my appointment but decided that the Inquiry should be a public inquiry under the Inquiries Act 2005. He announced this Inquiry and its Terms of Reference to the House of Commons on 9 June 2010. He told the House:

> *So why another inquiry? We know only too well every harrowing detail of what happened at Mid Staffordshire and the failings of the trust, but we are still little closer to understanding how that was allowed to happen by the wider system. The families of those patients who suffered so dreadfully deserve to know, and so too does every NHS patient in this country.*
>
> *This was a failure of the trust first and foremost, but it was also a national failure of the regulatory and supervisory system, which should have secured the quality and safety of patient care. Why did it have to take a determined group of families to expose those failings and campaign tirelessly for answers? I pay tribute again to the work of Julie Bailey and Cure the NHS, rightly supported by Members in this House.*

3 Hansard, 24 February 2010, Col 309
4 Hansard, 24 February 2010, Col 312

Why did the primary care trust and strategic health authority not see what was happening and intervene earlier? How was the trust able to gain foundation status while clinical standards were so poor? Why did the regulatory bodies not act sooner to investigate a trust whose mortality rates had been significantly higher than the average since 2003 and whose record in dealing with serious complaints was so poor? The public deserve answers.

The previous reports are clear that the following existed: a culture of fear in which staff did not feel able to report concerns; a culture of secrecy in which the trust board shut itself off from what was happening in its hospital and ignored its patients; and a culture of bullying, which prevented people from doing their jobs properly. Yet how these conditions developed has not been satisfactorily addressed.[5]

13 This is the summary of the final report of the Inquiry.

Scope of the Inquiry

Terms of Reference

14 The setting up of the Mid Staffordshire NHS Foundation Trust Public Inquiry was announced to Parliament by the then Secretary of State for Health, the Rt Hon Andrew Lansley CBE MP, on 9 June 2010.

15 The Terms of Reference for this Inquiry are as follows:

- *To examine the operation of the commissioning, supervisory and regulatory organisations and other agencies, including the culture and systems of those organisations in relation to their monitoring role at Mid Staffordshire NHS Foundation Trust between January 2005 and March 2009 and to examine why problems at the Trust were not identified sooner, and appropriate action taken. This includes, but is not limited to, examining, the actions of the Department of Health, the local strategic health authority, the local primary care trusts, the Independent Regulator of NHS Foundation Trusts (Monitor), the Care Quality Commission, the Health and Safety Executive, local scrutiny and public engagement bodies and the local Coroner;*[6]
- *Where appropriate, to build on the evidence given to the first inquiry and its conclusions, without duplicating the investigation already carried out, and to conduct the inquiry in a manner which minimises interference with the Mid Staffordshire NHS Foundation Trust's work in improving its service to patients;*

5 Hansard, 9 June 2010, Column 333

6 This list should also include predecessor bodies of these organisations, where relevant, in accordance with the time period the Inquiry is examining.

- *To identify the lessons to be drawn from that examination as to how in the future the NHS and the bodies which regulate it can ensure that failing and potentially failing hospitals or their services are identified as soon as is practicable;*
- *In identifying the relevant lessons, to have regard to the fact that the commissioning, supervisory and regulatory systems differ significantly from those in place previously and the need to consider the situation both then and now;*
- *To make recommendations to the Secretary of State for Health based on the lessons learned from the events at Mid Staffordshire; and to use best endeavours to issue a report to him by March 2011.*[7]

16 Because this Inquiry has, in accordance with its Terms of Reference, built on the conclusions and evidence of the first inquiry, it is important for this report to be read with the report of the first inquiry.

The first inquiry

17 As stated above, the Terms of Reference for this Inquiry include a requirement to build on the work and conclusions of the first inquiry into the care provided by Mid Staffordshire NHS Foundation Trust between January 2005 and March 2009.

18 That first inquiry was set up by the Rt Hon Andy Burnham MP, the then Secretary of State for Health, when he announced, in a written statement to the House of Commons on 21 July 2009 that he had appointed me to chair an independent inquiry into Mid Staffordshire NHS Foundation Trust.

19 There were a number of events that led to that first inquiry:

- In 2007, concerns were raised about the Trust's mortality rate as compared with other similar trusts. Then in April 2008 the HCC launched an investigation into the Trust, following what it regarded as a concerning reaction by the Trust to the mortality statistics and number of complaints. In March 2009 it published the report of its investigation, which was highly critical of the acute care provided by the Trust.
- During the course of the investigation, and following the publication of the HCC's report, there was an increasing public outcry led by a group of patients and patients' relatives who had experienced poor care at the hands of the Trust. This group, called Cure the NHS (CURE), was led by Julie Bailey, the daughter of Isabella Bailey, an elderly patient who had died in Stafford Hospital. CURE ensured that the issue of the standard of care provided by the Trust remained in the public consciousness, and it campaigned tirelessly for a public inquiry.

7 It was subsequently agreed with the Secretary of State that the extent of the material that had to be examined by the Inquiry made this completion date impractical.

- In a partial response to these publicly expressed concerns, over the course of 2009 the Trust set up an independent case notes review, led by Dr Mike Laker and subsequently managed by the primary care trust. The Secretary of State also commissioned his own reviews: by Dr David Colin-Thomé on the lessons to be learned in relation to commissioning of services; and by Professor Sir George Alberti on the specific issues surrounding emergency admissions at the Trust. Both prepared reports that were published at the end of April 2009.
- None of these reviews or reports satisfied the public concerns as represented by Julie Bailey and CURE, who continued to demand a public inquiry into the failings at the Trust.

20 Ministers did not at that stage agree to set up a public inquiry, but instead commissioned an independent inquiry into the care provided at the Trust. The terms of reference for the first inquiry were as follows:

- *To investigate any individual case relating to the care provided by Mid Staffordshire NHS Foundation Trust between 2005 and 2008* [later amended to March 2009] *that, in its opinion, causes concern and to the extent that it considers appropriate;*
- *In the light of such investigation, to consider whether any additional lessons are to be learned beyond those identified by the inquiries conducted by the HCC, Professor Alberti and Dr Colin-Thomé; and, if so:*
 - *to consider what additional action is necessary for the new hospital management to ensure the Trust is delivering a sustainably good service to its local population;*
 - *to prepare and deliver to the Secretary of State a report of its findings.*

21 As stated by the then Secretary of State, in his Written Ministerial Statement to the House of Commons on 21 July 2009, the focus of the first inquiry was to be on:

> *... ensuring that patients or their families have an opportunity to raise their concerns. It is important, given the events of the past, for those who depend upon the care provided by the trust to be confident that they have been listened to and that any further lessons not already identified by the thorough inquiries that have already occurred be learned.*

22 During the course of the first inquiry, documentary material was obtained from a wide variety of sources, including the Trust, the primary care trust (PCT) and other NHS bodies, the Care Quality Commission (CQC), the SHA, Monitor, CURE, the local authorities and the four local Members of Parliament. The first inquiry was contacted, directly or indirectly, by 966 individual members of the public and some 82 members of staff from the Trust, past and present, and between 2 November and 22 December 2009, the first inquiry heard oral evidence from 113 witnesses.

23 The first inquiry heard harrowing personal stories from patients and patients' families about the appalling care received at the Trust. On many occasions, the accounts received related to basic elements of care and the quality of the patient experience. These included cases where:

- Patients were left in excrement in soiled bed clothes for lengthy periods;
- Assistance was not provided with feeding for patients who could not eat without help;
- Water was left out of reach;
- In spite of persistent requests for help, patients were not assisted in their toileting;
- Wards and toilet facilities were left in a filthy condition;
- Privacy and dignity, even in death, were denied;
- Triage in A&E was undertaken by untrained staff;
- Staff treated patients and those close to them with what appeared to be callous indifference.

24 The first inquiry report was published on 24 February 2010. It contained damning criticism of the care provided by the Trust, drawing out a number of conclusions, including:

- There was a lack of basic care across a number of wards and departments at the Trust;
- The culture at the Trust was not conducive to providing good care for patients or providing a supportive working environment for staff; there was an atmosphere of fear of adverse repercussions; a high priority was placed on the achievement of targets; the consultant body largely dissociated itself from management; there was low morale amongst staff; there was a lack of openness and an acceptance of poor standards;
- Management thinking during the period under review was dominated by financial pressures and achieving FT status, to the detriment of quality of care;
- There was a management failure to remedy the deficiencies in staff and governance that had existed for a long time, including an absence of effective clinical governance;
- There was a lack of urgency in the Board's approach to some problems, such as those in governance;
- Statistics and reports were preferred to patient experience data, with a focus on systems, not outcomes;
- There was a lack of internal and external transparency regarding the problems that existed at the Trust.

25 One of the key issues raised in the report was the role played by external organisations which had oversight of the Trust. The report noted that:

The Inquiry has received a considerable number of representations that there should be an investigation into the role of external organisations in the oversight of the Trust. Concern is expressed that none of them, from the PCT to the Healthcare Commission, or the local oversight and scrutiny committees, detected anything wrong with the Trust's performance until the HCC investigation. While such an investigation is beyond the scope of this Inquiry, local confidence in the Trust and the NHS is unlikely to be restored without some form of independent scrutiny of the actions and inactions of the various organisations to search for an explanation of why the appalling standards of care were not picked up. It is accepted that a public inquiry would be a way of conducting that investigation, but also accepted that there may be other credible ways of doing so.[8]

26 One of the key recommendations arising from the first inquiry report was:

> *52. Having considered the evidence and representations referred to in Section H, I conclude that there is a need for an independent examination of the operation of each commissioning, supervising and regulatory body, with respect to their monitoring function and capacity to identify hospitals failing to provide safe care: in particular:*
>
> - *what the commissioners, supervisory and regulatory bodies did or did not do at Stafford;*
> - *the methods of monitoring used, including the efficacy of the benchmarks used, the auditing of the information relied on, and whether there is a requirement for a greater emphasis on actual inspection rather than self-reporting;*
> - *whether recent changes, including the 'Memorandum of Understanding' between Monitor and the Care Quality Commission (CQC), Quality Accounts and the registration of trusts by CQC, will improve the process by which failing hospitals are identified;*
> - *what improvements are required to local scrutiny and public engagement arrangements; and*
> - *the resourcing and support of foundation trust governors.*
>
> *53. This Inquiry has received many demands that there should be a public inquiry. One of the elements of such an inquiry, it has been suggested, should be the investigation of the external bodies mentioned above. I do not consider it is appropriate for me to suggest that a public inquiry (in the sense of an Inquiries Act inquiry) is the only way in which these issues can be addressed, but it is certainly a way in which it could be done.*

8 Independent Inquiry into Care Provided by Mid Staffordshire NHS Foundation Trust January 2005–March 2009, Volume 1, HC375-1 (24 Feb 2010), page 23, paragraph 75

Recommendation 16: The Department of Health should consider instigating an independent examination of the operation of commissioning, supervisory and regulatory bodies in relation to their monitoring role at Stafford hospital with the objective of learning lessons about how failing hospitals are identified.[9]

27 The DH and the Trust Board accepted the recommendations of the first inquiry in full.

28 In response, and to support all NHS organisations to learn from and respond to the recommendations of the report, the DH published three reports designed to help embed effective governance and detect and prevent such serious failures occurring again:

- *Review of Early Warning Systems in the NHS*, which described the systems and processes, and values and behaviours which make up a system for the early detection and prevention of serious failures in the NHS;[10]
- *Assuring the Quality of Senior NHS Managers*, which set out recommendations to further raise the standards of senior NHS managers;[11]
- *The Healthy NHS Board,* which set out guiding principles to allow NHS board members to understand the collective role of the board and individual role of board members, governance within the wider NHS and approaches that are most likely to improve board effectiveness.[12]

29 The Secretary of State accepted a recommendation to consider asking Monitor to de-authorise the Trust when the power came into effect.

30 The Secretary of State also accepted Recommendation 16 of the first inquiry report and proposed that I chair an inquiry on a non-statutory basis, with the presumption that it would sit in public.

What went wrong and where

31 As seen above, the Terms of Reference[13] require this Inquiry to examine the involvement of numerous agencies with the events at the Mid Staffordshire NHS Foundation Trust within a defined period: January 2005 to March 2009. In doing so, this report builds on the findings of the first inquiry and the previous report of the HCC, and only reconsiders what is said where new evidence has thrown more light on what occurred. While observations will be made about the conduct of the business of the Trust and on some of those responsible, this report does not amount to a complete rehearsal or review of what has been found not only by the

9 Independent Inquiry into Care Provided by Mid Staffordshire NHS Foundation Trust January 2005–March 2009, Volume 1, HC375-1 (24 Feb 2010), page 415, paragraph 52
10 DH00000000628 *Review of Early Warning Systems in the NHS: Acute and community services*, (February 2010), National Quality Board
11 Assuring the Quality of Senior NHS Managers – Final Report (24 Feb 2010), PricewaterhouseCoopers LLP
12 EMB/1 WS0000022551
13 See Annex A

first inquiry but also the HCC investigation and other reports. To have conducted such a review would have led to an unnecessary and disproportionate extension to an already complicated and lengthy process.

32 The Inquiry has been helped considerably by evidence from the Trust's patients, and those close to them, and has heard many harrowing stories. The principal focus of this Inquiry in receiving their evidence has been to understand their experiences of the wider system of the NHS in pursuing their complaints and concerns. Another principal purpose of this Inquiry has been to look at the interactions between the Trust and the various agencies which had responsibility for oversight, commissioning and regulation of healthcare services and professionals at the relevant time. For this reason it was not considered necessary to obtain or have regard to evidence from as wide a range of witnesses from within the Trust as might have been the case if this had been an inquiry focused on a formal investigation of its internal workings.

33 The interaction of the Trust with various other organisations has also been looked at. These are bodies which, while having no statutory, managerial or regulatory responsibilities in relation to the Trust's activities, had access to information which might have been helpful in detecting what was going wrong there or may have a contribution to make with regard to improvements in culture, training and support of healthcare professionals and managers working there.

34 It must be emphasised that it has not been within the Inquiry's remit to examine alleged failures of the system with regard to other trusts and services. Unhappily, the Inquiry received more than one request that it should do so, and all have had to be declined. Arguments were on occasion advanced that examination of events at other places would throw light on what went wrong in Stafford or in other parts of the healthcare system. To have explored such arguments by evidence would have been speculative and would have led to lines of enquiry in respect of which, once they were embarked upon, it would be difficult to know when it was appropriate to stop. In other words, this would have become not just a long inquiry but an endless one. The inability of the Inquiry to look into such matters, however, should not be taken to mean that I have made any determination that the matters of this nature raised were of no substance. I have simply decided that they were not to be regarded as within my Terms of Reference. In passing, I should observe that many of those who wrote to me with requests to look at issues arising elsewhere were clearly deserving of great sympathy, and their need to approach me in some cases bore witness to their inability to obtain satisfaction from the complaints and redress systems available to them.

35 I deal with the issue of whether any inferences may properly be drawn as to the existence of similar problems elsewhere in the service later in this Introduction (see 'Extrapolation' below).

Geographical and institutional limitations

36 The disaster of Stafford Hospital occurred in an NHS acute hospital provider trust, and it is the lessons to be learned from that which I have been asked to identify. Of necessity, this Inquiry has focused on the NHS in England and the arrangements for directly provided NHS care. NHS hospital care is also provided by independent providers through NHS funding arrangements. NHS providers share a regulator with providers of independently funded care. Different arrangements apply in Wales, Scotland and Northern Ireland for NHS care. Primary care is subject to a different regime. This report will not specifically address how the lessons from Stafford might be applied to those different parts of the health economy, but there are likely to be implications in the lessons and recommendations for other sectors which must be borne in mind in implementing them by those charged with doing so.

Lessons

37 The other main duty imposed on the Inquiry by its Terms of Reference has been to identify the lessons to be learned from the Stafford experience for the future, having regard to the system as it is now constituted. This has required the Inquiry to inform itself about the changes that have taken place since 2009. Given the pace of reform and procedural change during the lifetime of the Inquiry, this has been no easy task. The Inquiry sought to inform itself of those which have taken place since the close of the oral hearings and which are in the public domain. Wherever it has been deemed relevant, reference has been made to them in the text. This report should not, however, be understood as intending to offer a comprehensive and up to the minute account of the current position.

38 A number of organisations in existence during the period 2005 to 2009 have been abolished since, and others have been created. It has not been within the remit of the Inquiry to investigate the workings of these new bodies except to the extent thought necessary to inform the Inquiry about how the system now operates. That consideration has not extended to examine whether specific interventions in respect of other trusts or even the Trust have been deficient or effective, although the Inquiry has been invited to do so. This would not have been within its remit. However, in some instances the culture within the new system has been looked at and observations will be made about it.

39 Clearly some of the changes that have taken place have been the subject of considerable controversy, in particular the reforms to commissioning now enacted in the Health and Social Care Act 2012. It has not been within the remit of the Inquiry to examine the merits of the arguments for or against these reforms. There are many differing opinions on the best way to provide healthcare to the public in accordance with the founding principles of the NHS, but the focus of this Inquiry has been relentlessly on the need to protect patients from unacceptable and unsafe care. That should be possible to achieve whatever the system of provision. In general, it is unlikely to be structural changes in the system which enhance safety, although there may be many other reasons for making them. Within any system there is a need to

ensure a relentless focus on ensuring patient safety and the provision of at least a minimum quality of care. That should not be too much to ask of any system.

Recommendations

40 There are 290 recommendations in the report. They occur at various places throughout the report but have been grouped according to themes identified by the Inquiry, and are presented in a table in *Chapter 2* of this summary and in *Chapter 27* of the report. They are also highlighted in the report at the end of relevant chapters. Where possible, recommendations identify the organisation it is suggested should take them forward. Where, for whatever reason, this has not been thought possible it would be for the DH to ensure that they are taken forward. Some recommendations are of necessity high level and will require considerable further detailed work to enable them to be implemented. They seek to take account of the system as now structured. In correspondence with the Inquiry the DH confirmed that the recent reforms would not pre-empt consideration of them.

41 The experience of many previous inquiries is that, following the initial courtesy of a welcome and an indication that its recommendations will be accepted or viewed favourably, progress in implementation becomes slow or non-existent. It is respectfully suggested that the subject matter of this Inquiry is too important for it be allowed to suffer a similar fate. The suffering of the patients and those close to them described in the first inquiry report requires a fully effective response and not merely expressions of regret, apology and promises of remedial action. They have already been at the receiving end of too many unfulfilled assurances for that to be acceptable. What is required is a means by which it is clear not only which of the recommendations has been accepted, by whom, and what progress is being made with implementation, but above all how the spirit behind the recommendations is being applied. All organisations that are or should be involved in implementation should account for their decisions and actions in this regard. While the implementation process could benefit from coordination by the DH, many recommendations can be directly implemented by other bodies. While the theme of the recommendations will be a need for a greater cohesion and unity of culture throughout the healthcare system, this will not be brought about by yet further "top down" pronouncements but by engagement of every single person serving patients in contributing to a safer, committed and compassionate and caring service. Therefore, the first recommendation of the report relates to the potential oversight of and accountability for implementation of its recommendations:

42 It is recommended that:

- All commissioning, service provision, regulatory and ancillary organisations in healthcare should consider the findings and recommendations of this report and decide how to apply them to their own work;

- Each such organisation should announce at the earliest practicable time its decision on the extent to which it accepts the recommendations and what it intends to do to implement those accepted, and thereafter, on a regular basis but not less than once a year, publish in a report information regarding its progress in relation to its planned actions;
- In addition to taking such steps for itself, the Department of Health should collate information about the decisions and actions generally and publish on a regular basis but not less than once a year the progress reported by other organisations;
- The House of Commons Select Committee on Health should be invited to consider incorporating into its reviews of the performance of organisations accountable to Parliament a review of the decisions and actions they have taken with regard to the recommendations in this report.

Constitution of the Inquiry

Panel

43 No panel was appointed to sit with me. Accordingly the daunting task of fulfilling the Terms of Reference has been my responsibility and mine alone. Therefore, the narrative, analysis findings and recommendations are also mine and mine alone, arrived at having regard to all the evidence placed before the Inquiry.

Assessors

44 To assist me in that task I appointed a number of assessors, which I was entitled to do under Section 11 of the Inquiries Act 2005.[14] Their function has been to offer me advice on matters within their expertise. Three of the assessors assisted me during the first inquiry and therefore brought with them a direct experience of the issues exposed by it. One gave expert evidence at this Inquiry and, as did three other assessors, contributed to the seminars which formed part of the material gathered.

45 The assessors were appointed in two stages. The first group were involved from the outset of the Inquiry and were in a position to offer me explanations, context and advice on the evidence as it emerged allowing me a greater understanding of what I was being told. I have also benefited from their immense experience in various aspects of the healthcare and other systems in identifying the issues arising for the system. I did not invite them to attend the oral hearings, but they were provided with access to the transcripts. I did not think it necessary for the performance of their function to attend oral hearings, and it would in practice have been very difficult to find assessors of the authority and experience of this panel who would have been able to make the time available to attend the many weeks of hearings.

14 A list of assessors and a summary of their qualifications and backgrounds appears at Annex D in the main report.

46 The second group were appointed after the close of the oral hearings with the specific remit of advising me in relation to the likely effectiveness of recommendations I was proposing to make. Their task was not to propose any recommendations but to allow me to reflect with them on the extent to which the recommendations I wished to make would help to address the problems this sad story has revealed.

47 I have not thought it necessary or desirable to have prepared or to publish a note of my discussions with the assessors, and no written reports have been sought or provided. Their function has been to act as a sounding board and to challenge and advise me. It is not proposed to disclose the content of any advice, whether written or oral.

48 I must place on record my deep gratitude to the assessors for the patience and dedication with which they have gone about their tasks. I could not have completed the report without their assistance.

The legal team

49 Counsel to the Inquiry, Tom Kark QC, and his juniors, Ben Fitzgerald, Tom Baker and Joanna Hughes have performed with great distinction the onerous task of analysing the vast quantity of evidential material made available to the Inquiry and presenting evidence and submissions at the oral hearings. They have continued to assist me as legal advisers and have been of immense assistance in all the procedures that have been undertaken.

50 Both Counsel and I have been privileged to receive the constant help of the Solicitor to the Inquiry, Peter Watkin Jones, his principal assistants Sarah Garner, Luisa Gibbons, Catherine Henney and Isabelle Makeham and the rest of his team from Eversheds.[15] To them fell the task of the initial sorting and analysis of well over a million pages of raw material disclosed to the Inquiry by the core participants and others, approaching and interviewing witnesses, preparing witness statements and the general legal conduct of the Inquiry. They too are owed a huge debt of gratitude for making order out of potential chaos and allowing the Inquiry to be conducted in as orderly a fashion as possible.

51 This Inquiry, like most modern public inquiries, has been run on a strictly non-adversarial basis with the result that representatives of core participants were generally expected to propose lines of questioning they wanted to be pursued with the legal team. The core participants were entitled to raise with me any concerns and to apply to ask questions directly if not satisfied with the conduct of questioning by Counsel to the Inquiry. It is a significant tribute to the legal team that core participants felt it necessary to make such an application on extremely rare occasions.

15 A full list of the Solicitor's team, along with the rest of the Inquiry team, appears at Annex B in the main report.

The Secretariat

52 The Secretary to the Inquiry, Alan Robson, his deputy Catherine Pearson and his team have met the challenge of the setting up of the infrastructure, providing the face of the Inquiry to the public and coping with the myriad of tasks required to maintain and bring the process to a conclusion.[16] It may come as a surprise for some to appreciate that there is no effective established template for the setting up or administration of a public inquiry and, therefore, the team has had to start from scratch. I am sure I am not the first chair of an inquiry to wonder why it is necessary for the wheel to be reinvented in relation to the many administrative and logistical details without which an inquiry cannot function. However, Mr Robson and his team rose magnificently to this challenge. They deserve particular praise for their caring and sensitive support given to witnesses to the Inquiry, many of whom faced great difficulties in taking this step.

The core participants and their representatives

53 Thirteen organisations applied or were invited to be core participants. This status gave them access to evidential material in advance of it being adduced in evidence, and they were, as indicated above, able to suggest lines of inquiry to the legal team. They were entitled to be legally represented and to make submissions to the Inquiry. Without exception, they used these rights proportionately and constructively in a manner which was of great assistance.

Liaison between the Inquiry and the core participants and the public

54 The Inquiry, through the Solicitor and the Secretary's teams, sought to keep the core participants, and the wider public, informed of the conduct of its business as it has proceeded. This has largely been done through the Inquiry website, though there has been regular correspondence and meetings with core participants on procedural matters and with the wider public and press who have been in touch with the Inquiry Secretary's team in writing, in person and on the telephone. For the duration of the hearings, the whole Inquiry team was located and worked from the hearing venue at Stafford Borough Council Offices.

55 The website has also sought to inform relevant parties of the Inquiry's intentions and procedures as they have unfolded, rather than after the event. Procedural protocols and statements have been issued (after consultation as necessary) and posted to the Inquiry's website on issues such as procedures to be adopted, a media protocol, a protocol for seeking legal representation at public expense, a protocol on the issue of warning letters under Rule 13 of the Inquiry Rules 2006, together with other key documents, such as the issue of restriction notices, the circumstances of accepting new evidence after close of evidence, and the details of the Inquiry's costs.

16 A full list of the Secretariat appears at Annex B in the main report.

56 Evidence and submissions have also been made available online. All core participants were provided with advance notice through the Inquiry's database of the statements and exhibits of witnesses who were to give evidence and indeed of those with possibly relevant evidence to give, but where the Inquiry had decided not to call the witness in person. Schedules of the timetabling of witnesses to give oral evidence were made publicly available in advance of witnesses being called. The statements of witnesses and their exhibits have generally been made available to the public and press via the website on the day the witnesses gave oral evidence. A livenote transcript was taken of all evidence given and that was generally posted on the evening of the giving of evidence too. Submissions made by the legal representatives of the core participants and of Counsel to the Inquiry were also made available on the website.

Seminars

57 Following the end of the public hearings, I organised a series of seven seminars where invited speakers, attendees, members of the public and press had an opportunity to come and discuss various topics that I had set out on the Inquiry website. I commissioned papers and/or presentations from the invited speakers, and these are all available on the Inquiry website.

58 The seminars covered:

- Methods of regulation, which was held on 13 October 2011 in Manchester;
- The training and development of trust leaders, which was held on 18 October 2011 in Leeds;
- Information, which was held on 19 October 2011 in Leeds;
- Organisational culture, which was held on 25 October 2011 in London;
- Nursing, which was held on 31 October 2011 in London;
- Patient experience, which was held on 2 November 2011 in Stafford;
- Commissioning, which was held on 3 November 2011 in London.

59 All seven seminars were facilitated by Dr Sarah Harvey, who also produced a report of the seminars that was published in hard copy and is available on the Inquiry website.

60 I also undertook a small number of visits to healthcare organisations, and a list of those visited is set out at Annex E in the main report.

Witnesses

61 Some 164 witnesses gave oral evidence. In addition, a further 87 witness statements and 39 provisional statements were 'read' into the Inquiry's record and were accepted into evidence. The Inquiry took 352 individual witness statements in total but some of these were not deemed material or relevant to the Inquiry's business. Those who assisted the Inquiry by

re-living their experiences of poor care and poor handling of their complaints did so with great dignity, patience and care. I am indebted to them for their invaluable assistance and acknowledge the cost in suffering that must have been incurred by many of them in doing so.

62 The Inquiry also heard from a vast range of healthcare professionals, officials, politicians and others involved in the complexities of commissioning, performance management, oversight and regulation of the healthcare system. The experience will have been stressful for nearly all of them, but the Inquiry is grateful to all for their assistance. It would have been surprising if I had been able to agree with the recollections or views of every witness, but I am satisfied that without exception they were all doing their honest best to tell me the truth as they saw it.

63 Not all witnesses were asked to give oral evidence. In the main this was because what they had to say was sufficiently contained in a written statement and little additional benefit would have been obtained from oral examination. In one significant case, that of Mr Martin Yeates, the former Chief Executive of the Trust, he was excused from giving oral evidence for medical reasons, which I was satisfied, following receipt of a report of an independent medical examination commissioned by the Inquiry, rendered him unfit to attend to give oral evidence. He was, however, able to provide a substantial written statement to the Inquiry following an interview by the Solicitor to the Inquiry.

64 Two witnesses were excused, because of medical reasons, the normal requirement of giving their oral evidence in the Inquiry chamber in the presence of the public, but they were allowed to do so in a separate room and one from a separate location, with what they said being relayed live to the public.

65 The Inquiry also had the benefit of a range of expert evidence from witnesses appointed by the Inquiry as experts for this purpose. I would like to express my gratitude for their deep understanding of the system and its history that this evidence brought to the process.

Hindsight

66 Professor Sir Brian Jarman pointed out in his evidence to this Inquiry that at the Bristol Inquiry, in which he was a member of the inquiry panel, there were 120 mentions of the word "hindsight" in the evidence. The Bristol Inquiry report contained a section on hindsight. In the Foreword, the panel expressed the hope that the disaster that had been uncovered there would not be repeated:

It would be reassuring to believe that it could not happen again. We cannot give that reassurance. Unless lessons are learned, it certainly could happen again, if not in the area of paediatric cardiac surgery, then in some other area.[17]

67 Professor Jarman told this Inquiry that although he had doubts whether the DH would actually implement the recommendations of the Bristol Inquiry:

I did feel at least there would be no excuse in future for those responsible to continue to say, after the Bristol report was published, as they had said to us throughout the Bristol Inquiry, "with the benefit of hindsight".[18]

68 Unhappily, the word "hindsight" occurs at least 123 times in the transcript of the oral hearings of this Inquiry, and "benefit of hindsight" 378 times.

69 It is of course inappropriate to criticise individuals or organisations for failing to apply fully the lessons to be learned from the knowledge that is now available, and accepting in the light of that knowledge, not possessed at the relevant time, that more or earlier intervention should have occurred. It must be accepted that it is easier to recognise what should have been done at the time now that the enormity of what was occurring in the Trust is better known.

70 There is, however, a difference between a judgement which is hindered by understandable ignorance of particular information and a judgement clouded or hindered by a failure to accord an appropriate weight to facts which were known.

71 It has been said before and must be said again; I do not for a moment believe that those in responsible positions in the Trust or elsewhere in the healthcare system went about their work knowing that by action or inaction they were contributing to or condoning the continuance of unsafe or poor care of patients. What is likely to be less comfortable for many of those in such posts at the time is the possibility, and sometimes the likelihood, that whatever they believed at the time, they were not being sufficiently sensitive to signs of which they were aware with regard to their implications for patient safety and the delivery of fundamental standards of care.

Extrapolation

72 Some of the responses to Rule 13 letters, ie letters warning of potential criticisms, have asserted that it is impermissible to extrapolate from the events at Stafford a conclusion that such deficiencies are to be found elsewhere. This Inquiry has not, of course, investigated the state of affairs at any other trust. I have received several requests to do so from distressed

17 Jarman WS0000042749, para 38
18 Jarman WS0000042749, para 38

members of the public, but to have done so would not have been within my Terms of Reference. Therefore, I have been offered arguments that it would be unsafe in the absence of evidence to assume that significant changes are necessary to detect or prevent another such catastrophe.

73 The first point to make is that even if it were true that there were no other provider within the healthcare system which displayed the combination of deficiencies found at the Trust, it is of very grave concern that the extensive system of checks and balances intended to detect and prevent such failures did not work. Large numbers of patients were left unprotected, exposed to risk, and subjected to quite unacceptable risks of harm and indignity over a period of years. Whatever else can be said, the deficiencies at Stafford were wide in scale and adversely affected considerable numbers of patients and those close to them.

74 The second point is that it has not escaped the Inquiry's notice that even since the HCC report on the Trust there have been a series of highly concerning reports of experiences elsewhere containing echoes of what was experienced within the Trust. In the Patient Association's (PA's) closing submission to the Inquiry, they make reference to a number of highly critical reports, including: their 2009 report *Patients Not Numbers, People Not Statistics*; the 2009 report published by National Confidential Enquiry for Patient Deaths (NCEPOD), which reviewed the care of patients who died within four days of admission; the Alzheimer's Society report *Counting the Cost;* and their own report from 2010, *Listening to Patients, Speaking up for Change*.[19] There have been others, too, such as the Care Quality Commission (CQC) report in 2011 on dignity and nutrition for older people[20] and the well documented events of appalling care provided at Winterbourne View to name but two. Even if all the instances contained in the reports just mentioned are in some way isolated ones dependant on particular circumstances, they are suggestive that there are places where unhealthy cultures, poor leadership, and an acceptance of poor standards are too prevalent.

75 The third point is that the failure of the system to detect the deficiencies at the Trust and take effective action soon enough means that the public is unlikely to have confidence that "another Stafford" does not exist, in the absence of being convincingly persuaded that sufficient change has taken place.

76 Therefore, Stafford was not an event of such rarity or improbability that it would be safe to assume that it has not been and will not be repeated or that the risk of a recurrence was so low that major preventative measures would be disproportionate. The consequences for patients are such that it would be quite wrong to use a belief that it was unique or very rare to justify inaction.

19 CL0000001209, *Patient's Association closing submissions*, pages 2–3
20 *Dignity and Nutrition Inspection Programme,* (October 2011), Care Quality Commission, www.cqc.org.uk/sites/default/files/media/documents/20111007_dignity_and_nutrition_inspection_report_final_update.pdf

Similarity to others

77 An opposite argument was used, sometimes by those also espousing the extrapolation argument in other contexts, to justify inaction or a lack of a response. This was that matters of potential concern at Stafford, such as outlying mortality rates, concerns about governance, and staffing issues, could be found at many other places, and therefore were justifiably regarded as not being of particular significance or of requiring exceptional action.

78 In some instances, such an argument betrays a failure to appreciate the impact on patients and those close to them, of the deficiency in question. It is the institutional equivalent of the tolerance of poor care all too frequently seen and not challenged on some wards at the Trust. The fact that it might be typical of what happened elsewhere is cause for increased concern not reassurance. It is an argument which evidences a culture of habituation and passivity in the face of issues which may indicate real suffering. It is an attitude which would be unlikely to be persisted in if those adopting it were constantly to place an empathy for the predicament of patients at the forefront of their mind.

Standard of proof

79 In arriving at conclusions with regard to the relevant facts, the panel of a public inquiry finds itself in a different position to a court of law, whether civil or criminal. A court of law is required to make specific findings in relation to allegations made or charges before it in accordance with the relevant law. Issues are decided after the presentation of evidence and argument by each opposing party. In a criminal court charges may not generally be found proved unless the court is satisfied on the evidence so that it is sure of that matter. In civil proceedings the rule is generally that a fact will only be found proved if the court is satisfied of it on the balance of probabilities. In civil proceedings the more serious the allegation the more cogent will be the evidence required to prove it.

80 By contrast, at a public inquiry such as this one the process is inquisitorial, in that it takes the form of an investigation led by the inquiry and not by any of the parties. There are Terms of Reference but no more closely defined allegations or issues which have to be determined. There are no parties entitled as of right to call evidence of their own. The task of the inquiry is not to determine an allegation or a charge, and its findings are not determinative of civil or criminal liability. It is required to examine events that have occurred and identify lessons which in its opinion can be drawn from those events. It may as a matter of judgement identify criticisms it considers can be made of individuals or organisations arising from those events, but such findings are not binding on those criticised.

81 The Inquiries Act 2005 and the Inquiry Rules 2006 offer no specific guidance on the subject of the standard of proof to follow, beyond Section 17 of the Act which provides that subject to any provision of the Act or the rules:

... the procedures and conduct of the Inquiry are to be such as the chairman of the inquiry may direct.

82 The overriding requirement of the Act, set out in section 17(3), is that in any decision made by the chairman as to procedure or conduct of the Inquiry:

... the chairman must act with fairness and with regard also to the need to avoid any unnecessary cost ...

83 There is much legal authority on what is the appropriate standard of proof in civil and criminal proceedings, but this is of little relevance to an inquiry because of the differences in character between the public inquiry process and such proceedings mentioned above.

84 Some assistance can be gained from the rulings made by chairs of previous public inquiries on the issue.

85 In the Shipman Inquiry, Dame Janet Smith set out the approach of that inquiry to the standard of proof in her first report, in effect declining to be constrained by any one standard of proof:

9.43 In an inquiry such as this, there is no required standard of proof and no onus of proof. My objective in reaching decisions in the individual cases has been to provide an answer for the people who fear or suspect that Shipman might have killed their friend or relative. I have also sought to lay the foundation for Phase Two of the Inquiry. My decisions do not carry any sanctions. Shipman has been convicted of 15 cases of murder and sentenced appropriately. He will not be tried or punished in respect of any other deaths. Nor will my decisions result in the payment of compensation by Shipman. It is possible that relatives might recover damages from Shipman if they can show that Shipman has killed their loved one, but my decision that he has done so will not automatically result in an award of compensation against him. Accordingly, I have not felt constrained to reach my decisions in the individual cases by reference to any one standard of proof.[21]

86 At the Bloody Sunday Inquiry, Lord Saville of Newdigate rejected the application of the criminal standard of proof:[22]

8. In the context of the present Inquiry, there is no question of the Tribunal having any power to remove or diminish the rights, liberties or freedoms of anyone. It is not the function of an Inquiry of the present kind to determine rights and obligations of any nature. Its task, set by Parliament, is to inquire into and report upon the events on Sunday

21 *Shipman Inquiry First Report* (19 July 2002) chapter 9, www.shipman-inquiry.org.uk/fr_page.asp?ID=133
22 The Bloody Sunday Inquiry: Standard of Proof Ruling (11 October 2004)

30 January 1972 which led to loss of life in connection with the procession in Londonderry on that day, taking account of any new information relevant to events on that day. The Inquiry cannot be categorized as a trial of any description. Unlike the courts it cannot decide the guilt (or innocence) of any individual or make any order in its report. Our task is to investigate the events of Bloody Sunday, to do our best to discover what happened on that day and to report the results of our investigations. It accordingly follows that the considerations that led the courts in the cases cited to require proof to a very high standard before making orders that affected the rights, liberties and freedoms of individuals are no guide to the task entrusted to the Tribunal.

87 After referring to Dame Janet Smith's approach quoted above, Lord Saville went on:

10. We consider that these observations are apt in our consideration of the events of Bloody Sunday ...

17. In our view therefore the cases cited to us do not provide any support for the proposition that as a matter of principle we cannot make any findings implying criminality unless we are satisfied to the criminal standard of proof or of serious misconduct unless we are satisfied to the enhanced civil standard.

18. As we have said earlier, since we are an Inquiry and not a Court (criminal or civil) we cannot give a verdict or pass a judgement on the question whether an individual was guilty of a specific crime or legally recognised serious wrongdoing. For the same reason the terminology and requirements of the criminal or civil law are largely inapplicable. Thus it seems to us that we can and should reach conclusions without being bound by rules designed for court cases, such as who has the burden of proof and the strict rules of evidence ...

88 Referring to a judgment in a Canadian case[23] he said:

19. ... As he pointed out, the findings of a commission of inquiry relating to an investigation are simply findings of fact and statements of opinion reached by the commission at the end of the day; and though they may affect public opinion, they are not and cannot be findings of criminal or civil responsibility.

89 Lord Saville considered and rejected a submission that not to apply a high standard of proof would be unfair to the individuals concerned:

22. The Inquiry is indeed concerned with matters of the greatest seriousness. The question whether the shooting of civilians by soldiers was or was not justified is central. The very subject matter of the Inquiry raises the possibility that individuals may be the subject of

23 *Canada (Attorney-General) v Canada (Commission of Inquiry on the Blood System)* 1997 3 S.C.R. 440

the most serious criticism and there may well be wide publicity, though it should be noted that most of those concerned have been granted anonymity. But for the Tribunal to conclude that while it was not sure, nevertheless it seemed probable that a particular shooting was deliberate and unjustified (objectively and subjectively) could hardly create or increase a risk of prosecution; indeed it would be more likely to have the opposite effect. Furthermore, apart from the reference to the possible risk of prosecution, no attempt was made to explain what 'serious consequences' would follow were the Tribunal not to apply the suggested standards of proof, save that it was also suggested that the media would be likely to misrepresent the views of the Tribunal, and categorize the individual as being guilty without reference to the degree of confidence or certainty expressed by the Tribunal in making any findings implying criminality or serious misconduct. The fact (if such it be) that the media may misrepresent the views of the Tribunal does not seem to us to be a sound or satisfactory basis for requiring the Tribunal to refrain from expressing those views.

23. In our view, provided the Tribunal makes clear the degree of confidence or certainty with which it reaches any conclusion as to facts and matters that may imply or suggest criminality or serious misconduct of any individual, provided that there is evidence and reasoning that logically supports the conclusion to the degree of confidence or certainty expressed, and provided of course that those concerned have been given a proper opportunity to deal with allegations made against them, we see in the context of this Inquiry no unfairness to anyone nor any good reason to limit our findings in the manner suggested ...

24. It was also submitted that there would be no point in reaching conclusions on matters implying criminality or serious misconduct, unless we were sure beyond a reasonable doubt. We do not understand this submission. We are asked to investigate and report on an event that took place some three decades ago, where on any view soldiers of the British Army shot and killed (and wounded) a number of civilians on the streets of a city in the United Kingdom and where the question whether or not they were justified in doing so has been the subject of such debate ever since that it led to the institution of this (the second) Inquiry some thirty years later. It seems to us that it would be quite wrong to confine ourselves in relation to this central part of the Inquiry to making findings where we were certain what happened. On the contrary, it is in our view our duty to set out fully in our Report our reasoned conclusions on the evidence we have obtained and the degree of confidence or certainty with which we have reached those conclusions. We are not asked to report only on these central matters on which the evidence makes us certain.

27 ... we are not persuaded by the arguments that seek to impose on us the criminal or enhanced civil standard of proof in relation to findings implying criminality or serious misconduct falling short of criminality. We should emphasise, as we have made clear on numerous occasions during the course of the Inquiry, that this does not mean that we shall entertain or allow to be pursued allegations of this kind which have no sensible

foundation at all or in respect of which the individual concerned has not been given a proper opportunity to answer.

90 The effect of this ruling was that the inquiry could make findings of fact while describing the degree of confidence with which those were made. This was not thought to be unfair, provided there was a foundation of evidence and a logical basis for the finding and the individual to whom the finding was adverse was given a fair opportunity to answer the allegation.

91 It is right to note that both the Shipman and the Bloody Sunday inquiries were set up under the now repealed Tribunals of Inquiry (Evidence) Act 1921, but nothing appears to turn on this.

92 The Baha Mousa Public Inquiry was set up under the Inquiries Act 2005. Sir William Gage, after hearing submissions, gave a ruling on the standard of proof to be applied. He ruled that he would apply the civil standard of proof. His reasoning appears in the following passages:[24]

18 All counsel stressed that in making my findings I am required to act fairly. Of course, I am well aware of the need to be fair to soldiers and others whose reputations and careers may be affected by my findings. Throughout the Inquiry I have endeavoured with Counsel to the Inquiry to ensure that those who may be open to criticisms are treated fairly and I am grateful to Mr Singh for his endorsement that the level of natural justice afforded to those who may be criticised has been 'above and beyond' the strict requirements of the 2006 Rules.

19 I must also be fair to the detainees who, on any view of the evidence I have so far heard, suffered serious and traumatic injuries following their arrest and detention in the TDF at Battlegroup Main between 14 and 16 September 2003. In addition, this is a Public Inquiry and it is in the public interest that my findings in the Report are expressed in such a way as can be readily understood as my judgement on what occurred, who was responsible and why I have made recommendations. In my opinion, this can best be achieved by adopting the flexible and variable standard of proof as applied in the Shipman Inquiry.

20 I recognise that in relation to some issues in this Inquiry, the more serious the allegation the more cogent must be the evidence to support a finding of wrongdoing. I must as a matter of fairness bear in mind the consequences of an adverse finding to any individual against whom serious allegations are made. However, by section 2 of the 2005 Act, I have no power to determine criminal liability, and the mere fact that criminal culpability might be inferred from my findings, does not in my judgement mean that I must adopt the criminal standard in making findings of fact. On the contrary, I think that

24 *The Report of the Baha Mousa Inquiry: Volume 1*, HC 1452-I (8 September 2011), chapter 6

the usual starting point will be to apply the civil standard but taking account of the 'inherent improbability' concept where it properly applies.

21 There are some cases where criminal conduct is considered in the criminal courts applying the criminal standard of proof, the facts of which arise in later civil litigation where the balance of probabilities standard falls to be applied. In order properly to report who is responsible, in my judgement, I must reserve to myself the right to state, where I find the evidence sufficient, that I find a fact proved on a balance of probabilities. To do otherwise would necessarily be to limit my findings of responsibility to the high criminal standard.

22 This does not mean, however, that I shall disregard the criminal standard of proof. There may be factual issues involving allegations of serious misconduct against identifiable individuals, where I shall wish to make clear that although I am satisfied on the balance of probabilities that an individual was involved in misconduct, the evidence is not sufficient to establish that fact to the criminal standard. There may equally be factual issues where I am satisfied to the criminal standard either that an individual was involved in particular misconduct or that he can be exonerated of such misconduct. In such cases, I may again think it right to make clear in my report that I am able to reach those findings to the criminal standard. The important point is that where issues of misconduct are concerned, I must make clear the standard of proof (be it civil or criminal) to which I have been satisfied in making the relevant finding.

23 So far as all other allegations or factual disputes are concerned, in applying the balance of probabilities standard of proof the concepts of 'inherent improbabilities' and 'the commonsense approach' [sic] *when reaching findings are concepts with which all judges of fact at first instance are familiar. These are factors which I shall have well in mind when reaching findings of fact on a balance of probabilities.*

24 During the course of oral argument I canvassed with all counsel whether or not I am entitled to make comments expressing suspicion or, some other such phrase, that an allegation is true. Mr Singh submitted that I am entitled to do so; others disagreed. Mr Beer submitted that I have no power to do so because my power is only to determine the facts (s.24(1)(a) of the 2005 Act).

25 I do not accept that I may not make such comments. In my opinion the terms of s.24(1)(a) do not restrict me from doing so. In any event, as Mr Singh pointed out, s.24(1) of the 2005 Act provides that 'The report may also contain anything else that the panel considers relevant to the Terms of Reference'. I do, however, accept and stress that by making a comment of that nature I would not be making a finding of fact. I further accept that the power to make such a comment should be exercised sparingly. Circumstances in which I will feel constrained to do so will, I believe, be comparatively rare.

93 It is to be noted that although Sir William decided that in principle he would be applying the civil standard of proof, he considered he had power to make comments not amounting to findings of fact in the nature of expressions of suspicion.

94 Sir William appears to have understood the approach of the Shipman Inquiry to have been to apply the "flexible" civil standard of proof. The passages from the Shipman report quoted above suggest that a broader approach was taken; Dame Janet explicitly said she would not be constrained by the requirements of "any one" standard of proof.

95 Looking at the overall effect of how previous inquiries have approached the matter, together with the current Inquiries Act and Inquiry Rules, the following principles may be gleaned:

- It is for the chairman of the inquiry to decide on the approach to be taken to findings of fact, criticism and recommendations as part of his role in determining the procedure of the inquiry.
- Even in inquiries which have to address allegations of extremely serious crimes, there is no place for the application of the criminal standard of proof.
- The context of the task set for the inquiry is important in deciding what the proper approach to making findings may be.
- An inquiry should not be inhibited from setting out its findings and opinions based on those findings by adherence to particular standards of proof.
- An inquiry is free to express its findings as it sees fit, provided that they are logically founded on the evidence, the basis of the finding is made clear, and a person adversely affected by a finding has had a fair opportunity to deal with it.

96 While the present Inquiry concerns events which had caused untold distress to many patients and their families and considerable public concern about the standard of service in our hospitals, it is not an investigation into the alleged commission of criminal offences. It concerns the apparent deficiencies in a system which allowed poor care and treatment to be given which may have caused harm to numbers of patients. Inevitably, it is likely that large numbers of individuals had a part to play in this, none of whom individually could have prevented the totality of what occurred. In the course of analysing what happened and why, inevitably, it will be necessary to consider what could have been done better by individuals and organisations. This is a necessary part of identifying the lessons to be drawn.

97 One other important difference between this Inquiry and the others is that its Terms of Reference require it:

> *where appropriate to build on the evidence given to the first inquiry and its conclusions, without duplicating the investigation already carried out.*

98 Therefore, the Inquiry is required, where it considers it appropriate, to proceed on the basis of evidence already given and conclusions reached in a previously published report written by the same chairman.

99 As already stated, no findings of fact or criticism made in this report are determinative of any form of civil or criminal liability. The duty of the Inquiry is to set out its conclusions about what happened, along with any observations it may have on what happened by way of comment or criticism and to offer what in its opinion are relevant recommendations. It should not be inhibited from doing so by reason of any particular standard of proof. It must, however, only make comments and criticisms which it concludes are fair, and should not do so unless those affected by criticism have had a fair opportunity to deal with it through the Rule 13 process.

100 Taking all these considerations into account, I have concluded that:

- The Inquiry should make findings based on the evidence before it, taking into account the findings of the first inquiry. In all instances, the Inquiry's findings must be guided by what is fair.
- Much evidence of what happened has not been contradicted. Where such evidence is not contradicted the Inquiry is likely to accept it unless it is inherently improbable, in which case this will be made clear.
- Where there are issues in relation to what happened, all the evidence relevant to that issue will be considered and taken into account. No particular standard of proof will be applied, but the Inquiry will find the facts on the basis of the evidence that it has preferred. A common sense approach will be adopted whereby inherently improbable assertions will be regarded with more caution than inherently likely ones.
- Where it is decided in relation to an important event that it is only possible to say it may have occurred, this will be made clear. The narrative of the report will make clear what the Inquiry has concluded occurred and will refer to evidence supporting that conclusion. As this is a report not a court judgment, a full account of the reasons for preferring the evidence cited will not always be given.
- Although there are no strict rules of evidence other than the overriding requirement of fairness, I will bear in mind that different weight may have to be afforded to different types of evidence.
- Criticisms of organisations and individuals may appear either in the course of a narrative account of what happened or separately. They may either be made explicitly or be implied. Where a criticism is made or implied, this will be the result of the Inquiry forming an adverse opinion arising out of the finding of fact. That opinion and the resulting criticism are a matter of judgement and not a matter for which proof is required. An explanation of the significance of criticisms in this report appears below.

Responsibility and criticism

Procedure

101 Where the inclusion of a significant potential criticism of an individual or organisation was being considered by me, they were notified of this under Rule 13 of the Inquiry Rules 2006 and offered an opportunity to respond. The notice was accompanied by a schedule prepared by Counsel to the Inquiry summarising the nature of the criticism and giving references to the evidence thought to support such a criticism. The Inquiry Rules 2006 provide that a duty of confidentiality is owed by the Inquiry and the recipients of such notices to each other in respect of such notices. This means that each has a duty not to disclose the existence of or content of the notice without the permission of the other. Recipients were invited to apply to the Inquiry for a waiver permitting them to share notices with those from whom they wished to receive assistance in formulating their replies. A large number of such applications were made and almost all granted on condition that the third parties signed a form of undertaking to maintain the confidence.

102 The requirements of Rule 13 of the Inquiry Rules 2006 are such that sharing large extracts from the draft report would have been impracticable, distracting and undesirable. This had the unfortunate result that some potential criticism had the appearance of being more severe than was in fact the case once the criticism is seen in its context. Likewise some recipients were concerned that they may have been singled out for criticism that could equally apply to others, not knowing that similar notices had been sent to others.

103 Some of the recipients had not given evidence to the Inquiry and had not been asked to. A particular group in this category were former Ministers; in their case, notices were served at the specific suggestion of the DH, which considered that some proposed criticisms were in fact criticisms of them. I had not previously been of the view that these criticisms were of Ministers for the reasons given below. Having considered the helpful responses I received from former Ministers, I remain of that view.

104 Some recipients of notices, both among those who had given evidence and those who had not, complained that the matter of criticism had not been put to them during the hearing and therefore they had not had an opportunity to respond to it. This indicated a failure to understand the purpose of the Rule 13 process, which is to provide a very specific and fair opportunity to individuals and organisations to respond to proposed criticism. The process has demonstrated its value in this Inquiry. I received many thoughtful and well constructed responses offering an analysis of the evidence, and in some cases new evidence, relevant to potential criticisms. I paid very careful attention to all the responses and have taken them fully into account in my final conclusions. Many modifications were made to the draft report as a result.

105 Some recipients asked that they be given sight of any revision of the potential criticism before publication of the Inquiry report. I declined to do so; first because the Rules do not provide for such a facility, and second because it would have been impracticable and undesirable. Such a process would inevitably have led to a virtually endless exchange of drafts and submissions, making the Inquiry process even longer than it already had been. For better or for worse, it is I who have been charged with the task of assessing the evidence and drawing my conclusions and that is a task I must complete with fairness, due care, and within as reasonable a timescale as possible. Any new evidence taken in to account in this way has been published on the Inquiry website.

General observations

106 There is a tendency when a disaster strikes to try to seek out someone who can be blamed for what occurred, and a public expectation that those held responsible will be held to account. All too frequently there are insufficient mechanisms for this to be done effectively. A public inquiry is not a vehicle which is capable of fulfilling this purpose except in the limited sense of being able to require individuals and organisations to give an explanation for their actions or inaction.

107 The evidence to this Inquiry has shown that we have still not managed to move successfully away from the culture of blame which Professor Sir Liam Donaldson, in *Organisation with a Memory,*[25] and Professor Sir Ian Kennedy, in the report of the Bristol Inquiry,[26] were so keen to banish. The understandable human need to identify one or more people to be held to account means that whenever something goes wrong a hunt starts, and the larger the disaster the more pressure there is. Thus a factor in the pressure leading to this Inquiry was a wish to see people brought to account, whereas if an inquiry is to fulfil its main purpose it has to identify lessons to be applied.

108 On the whole, the purpose of identifying where individuals have fallen below relevant standards should be to show examples of conduct or judgements to be avoided in future. In a system failure as widespread as that identified in this Inquiry, it becomes a futile exercise to undertake; so many are in one sense accountable, it is far more effective to learn rather than to punish. To place too much emphasis on individual blame is to risk perpetuating the illusion that removal of particular individuals is all that is necessary. That is certainly not the case here. To focus, therefore, on blame will perpetuate the cycle of defensiveness, concealment, lessons not being identified and further harm.

25 LD/5 WS0000070414–5
26 The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984–1995: Learning from Bristol (July 2001) The Bristol Royal Infirmary Inquiry

Approach to criticism in this report

109 It must be remembered that the inquiry mechanism is not equipped to determine individual responsibility by way of anything akin to a "trial". Individuals and organisations may be called to provide evidence, may have legal representation and may have the opportunity to respond in accordance with the Inquiry Rules 2006 and procedure to potential criticisms, but they cannot defend themselves as they could in adversarial proceedings – by cross-examination of critical witnesses, or presentation of evidence they choose to call in their defence – and they only have a limited right to make representations to the Inquiry. An Inquiry does not and cannot determine civil or criminal liability. Therefore, where comments or conclusions are made which are or might be interpreted as being critical of individuals, these serious limitations arising out of the nature of the process must be borne in mind.

110 This Inquiry is charged to investigate the deficiencies in the system which allowed the events of Mid Staffordshire to pass unnoticed or without effective reaction for so long. This is not a case where it was ever going to be possible or permissible to find that an individual or a group of individuals was to blame for this. When examining what went wrong in the case of a systems failure as complex as that surrounding the events in Stafford, the temptation of offering up scapegoats is a dangerous one which must be resisted. To do this would be to create the fiction that the behaviour of one person, or a small group of people, would have made all the difference and conclude that the easy answer to the problem is to appoint better performing individuals. It was not a single rogue healthcare professional who delivered poor care in Stafford, or a single manager who ignored patient safety, who caused the extensive failure which has been identified. There was a combination of factors, of deficiencies throughout the complexity that is the NHS, which produced the vacuum in which the running of the Trust was allowed to deteriorate.

111 The principal factors concluded to have been involved in this systems failure are examined in the chapters of the report. It has been necessary to examine particular examples of performance of individuals and organisations to demonstrate the conclusions. Such conclusions have been arrived at after consideration of all the evidence before the Inquiry, including responses to warnings issued under Rule 13 of the Inquiry Rules 2006. It is not practical or proportionate, even in a report of this length, to recite all the evidence relevant to every point, but to the extent appropriate to the matters considered the evidential basis for those conclusions is made clear in the text. Other evidence could often have been identified. In many cases where critical comment is made, examples of others acting in a similar fashion could often have been found. The unpalatable truth is that there is much for all who work in healthcare to learn from the narrative in this report in terms of reflecting on their own work, attitudes and collective culture.

112 Therefore, critical comments will be made about individuals and organisations, policies and cultures. It is extremely important that these are seen with these matters in mind. Much will

be said about culture in the report. Individuals and indeed organisations acting in accordance with a culture, even a negative or unhealthy one, cannot always be held personally responsible for doing so.

113 The most important task of an inquiry such as this is to identify the lessons to be learned. Such lessons can include, and they do in the report, ways in which particular matters of administration, management, or implementation of policy could have been done better. Such points can be and often are illustrated by reference to the activities of particular individuals. Such a narrative may appear to be critical of the individuals or organisations concerned, but unless the context specifically states to the contrary, it should be borne in mind that the report is written with the benefit of hindsight, in full knowledge of the appalling care provided at the Trust and an appreciation of its consequences for patients. A statement in the report that something might or should have been done differently is not in itself a suggestion of negligence or of a breach of a duty existing at the time. Such critical comment is not intended, unless the contrary is clear from the context, to suggest that many others would not have acted in the same way if presented with the same set of circumstances at the time.

114 The fact that a critical comment is made about some action of an individual or an organisation does not necessarily mean that there are not many positive aspects to their work and contribution to healthcare. Many of those about whom some critical comment has been made have been involved in making significant changes for the better. Many have offered notable insight to the Inquiry, and have evidenced a genuine desire to effect improvements in the service and the system providing it, often through thoughtful contributions about possible changes for the future. This makes it all the more important for the report to be read as a whole. What are perceived to be critical comments should not be taken out of context or in isolation from the rest of the report. In an inquiry required to focus on what went wrong and what needs to be changed it is simply inappropriate to qualify every critical comment with a reference to unrelated positive points. It is the unhappy task of an inquiry to focus on what went wrong, and not on what went right.

115 The report also contains more general observations about the effect of certain policies and their implementation. If there is one central message to emerge from this Inquiry it is that the safety of patients and the requirements of fundamental standards are obligations which need to transcend particular policies and to permeate all considerations within the system. Nothing in this report is meant to question or analyse the wisdom or appropriateness of individual policies, ranging from the creation of the FT concept through to the Coalition Government's present reforms. It is not intended to suggest that any Government or any Secretary of State for Health, or any of their junior Ministers did not intend to maintain standards of safety and minimum care. Clearly there are many different ways in which healthcare can be delivered to the public, and it is well beyond the remit of this Inquiry to debate the respective merits of the various approaches taken by different Governments. It is in any event unrealistic to lay personally at the door of Ministers responsibility for the detail of ensuring that the implementation of a policy does not prejudice safety or effective delivery of minimum standards, unless they have received advice on that subject which they ignore. The DH is a remarkable combination of policy making, administration and executive NHS management, which makes recognition of the reality of the practical limits of Ministerial responsibility important, whatever may be the constitutional theory.

The structure and style of the main report

116 Given the complexity of the system, it has been the task of the Inquiry to examine the overlapping functions of the various organisations within it, and there has been no single obvious way in which to structure the main report. The approach taken has been to start with a consideration of warning signs (*Chapter 1: Warning signs*) that in retrospect existed and could have suggested that the Trust was the subject of serious deficiencies in relation to the provision of a safe and effective service. This chapter seeks to proceed in roughly chronological order, but, where a strict date order of events might not assist, some themes are pursued as a whole.

117 The report then proceeds to pick out some matters concerning the governance and culture of the Trust. It must be emphasised that this is not intended to be a comprehensive examination of all that went wrong there: this report must be read with the report of the first inquiry and the report of the HCC for a full understanding of that.

118 There follows an examination of the role played by local scrutiny and patient and public involvement groups, the commissioners, the SHA, and the regulators with a view to establishing what went wrong, followed by a consideration of the involvement of other agencies.

119 Finally, there follows a section dealing with themes for the present and future, arising out of what went wrong.

120 Of necessity, some events and evidence are referred to in more than one chapter. While an attempt has been made to keep repetition to a minimum, it is necessary in some contexts to assist in understanding.

121 Evidential references are given for all statements of fact and quotations in the report. Further detail as to the format of references used in this report appears on the Inquiry's website. In general unless the context makes the contrary clear, I have accepted the evidence recited. While I have had regard to all the evidence admitted and the submissions made, this already long report would have been unmanageable if all evidence relevant to each point were recited or referenced or if a fully reasoned decision was given for each issue of fact requiring determination. On the few occasions where there have been significant disputes about fact I have sought to give a fuller analysis for my conclusion. It is important when considering my recitation of facts, comments, criticisms and conclusions to read them in context, just as the report must be read as a whole.

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ISBN 978-0-10-298147-6

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1. Summary of findings

Warning signs

1.1 During the course of both the first inquiry and the present there has been a constant refrain from those charged with managing, leading, overseeing or regulating the Trust's provision of services that no cause for concern was drawn to their attention, or that no one spoke up about concerns.

1.2 This Inquiry has examined some of the more significant issues that were in fact identified or identifiable throughout the period leading up to the publication of the HCC report. These include the following:

- Loss of star rating – In 2004, the Commission for Health Improvement (CHI) re-rated the Trust, and it went from a three star trust to zero stars. The SHA knew not only of the loss of rating, but also of the factors likely to have been behind this: failure to meet targets for elective surgery, outpatient waiting times, cancer waiting times and financial performance. A "Stars Recovery Plan" was produced by the Trust which analysed the reasons for the change. The evidence suggests that officials from the Shropshire and Staffordshire Strategic Health Authority (SaSSHA) were unconcerned at these developments, and thought that the loss of stars was mainly due to poor record keeping and relied on results of the balanced scorecard. Yet the SHA, as with other organisations in the system, relied on the star ratings as an assurance that the quality of service was adequate. Indeed, it was intended to be the principal measure in that regard.

- Peer reviews – Peer reviews, including the Cancer Peer Review in 2005, the Care of Critically Ill and Critically Injured Children's Peer Review in 2006, and a follow up of the Children's Peer Review, were conducted during this period. Each of these reviews identified a number of concerns, often serious concerns, with the Trust's ability to deliver a safe service, and raised questions about management capability. The Inquiry has heard evidence to the effect that it was unclear who had responsibility for following up peer review reports.

- HCC reviews – In October 2006, the HCC published its own national review of children's services, which stated that the Trust did not meet the requirements or the reasonable expectations of patients and the public. In response, the Trust explained that this was partly due to a lack of data submitted, and that an action plan for improvement had been developed.

- Auditors' reports – During the relevant period, auditors' reports identified and reported to the Board serious concerns about deficiencies in the Trust's risk management and

assurance systems and made serious criticisms which called into question the accuracy and reliability of the Trust's compliance with standards. To any reasonably informed reader, the findings of this report would or should have called into question the competence of senior management and leadership at the Trust. The findings would or should have been of serious concern to the HCC and, in the context of an application for FT status, to Monitor and the DH.

- Surveys – The HCC commissioned annual surveys of staff and patient opinion conducted by the Picker Institute. The results of the survey taken for the previous year were published in about April the following year. The 2007 inpatient survey, while identifying many areas in which the Trust did well or performed satisfactorily, in several areas rated the Trust as being in the worst performing 20% in the country.

- Whistleblowing – It is clear that a staff nurse's report in 2007 made a serious and substantial allegation about the leadership of A&E. This was not resolved by Trust management. These issues were not made known by the Trust at the time to any external agency, but they were known to the Royal College of Nursing (RCN) because of its involvement with the personnel involved.

- The Royal College of Surgeons (RCS) report in January 2007 – The RCS reached critical conclusions about the operation and management of the Trust's surgical department, which it described as "dysfunctional". The report itself was known at the time only to the Trust and the relevant staff, and the Royal College. It showed a state of affairs which would have been expected to cause serious concern to the public, and any regulator, if known to them.

- The Trust's financial recovery plan and the associated staff cuts – Savings in staff costs were being made in an organisation which was already identified as having serious problems in delivering a service of adequate quality, and complying with minimum standards. Yet no thought seems to have been given in any part of the system aware of the proposals to the potential impact on patient safety and quality. There is no evidence that any effective questioning of this nature was undertaken. No detailed scrutiny of the possible impact of such changes seems to have been conducted by the SHA.

- The Trust's application for FT status – While the process of assessing such applications was, it is now accepted, largely focused on financial and governance rather than quality issues, the concerns that were made apparent by it about the Trust had potential implications for the standard of care delivered. The senior leadership of the SHA was aware of critical diagnostic findings, and yet did not think to look at whether a trust with such problems was actually delivering safe and acceptable care. Further, although the management was changed, there was no sense of urgency evinced by the SHA leadership with regard to the need for the newly installed management to make and evidence significant improvements. The assessment process leading up to the Minister giving his support did

not provide him with adequate information. While the HCC was looking into concerns that eventually led to the HCC setting up its investigation, it remained unaware at national level that an application for FT status was pending. Monitor remained unaware of the HCC's concerns about the Trust until after it authorised the Trust as an FT. The HCC's regional team was aware of the application but had not communicated that information to HCC Head Office.

- The HCC investigation – A formal investigation of the type launched by the HCC into this Trust was an unusual event, only embarked upon where there was serious cause for concern. The reaction of other bodies responsible for oversight and regulation was to await the outcome of the investigation and to rely on the HCC to inform them of matters requiring the urgent attention, rather than to consider for themselves what was wrong and what if anything, needed to be done for the protection of patients.

1.3 The above is only part of the story demonstrating the warning signs that were emanating from the Trust during this period and the corresponding reaction from external agencies. An examination of the evidence the Inquiry has heard reveals a pattern of concerns which, taken together, and in some cases even singly, such as certain examples of the systemic failure to deliver proper care to one patient, showed that there were serious systemic issues at the Trust requiring a degree of urgent and effective attention which they were not receiving.

Analysis of evidence

1.4 The Inquiry report examines what each organisation knew, or should have known, which might have been expected to give cause for concern or further inquiry, and to what extent, if any, action was taken to address these concerns.

The Trust and the Trust Board

1.5 The problems at the Trust identified by the HCC in its investigation and subsequently by the first inquiry's report were longstanding and apparently intractable. It was clear to the new Chair and Chief Executive on their arrival in 2004 and 2005 respectively that this was the position.

Negative culture

1.6 While it is clear that, in spite of the warning signs, the wider system did not react to the constant flow of information signalling cause for concern, those with the most clear and close responsibility for ensuring that a safe and good standard care was provided to patients in Stafford, namely the Board and other leaders within the Trust, failed to appreciate the enormity of what was happening, reacted too slowly, if at all, to some matters of concern of which they were aware, and downplayed the significance of others. In the first report, this was attributed in a large part to an engrained culture of tolerance of poor standards, a focus

on finance and targets, denial of concerns, and an isolation from practice elsewhere. Nothing I have heard in this Inquiry suggests that this analysis was wrong. Indeed the evidence has only reinforced it.

1.7 The Trust's culture was one of self promotion rather than critical analysis and openness. This can be seen from the way the Trust approached its FT application, its approach to high Hospital Standardised Mortality Ratios (HSMRs) and its inaccurate self declaration of its own performance. It took false assurance from good news, and yet tolerated or sought to explain away bad news.

Professional disengagement

1.8 Consultants at Stafford were not at the forefront of promoting change. The Inquiry heard evidence which added justification to the view formed at the first inquiry that clinicians did not pursue management with any vigour with concerns they may have had. Many kept their heads down. A degree of passivity about difficult personnel issues is all too common in the NHS as, perhaps, elsewhere. However, a system that is safe for patients requires a much more rigorous approach. The Trust lacked a sufficient sense of collective responsibility or engagement for ensuring that quality care was delivered at every level.

Patients not heard

1.9 Trust management had no culture of listening to patients. There were inadequate processes for dealing with complaints and serious untoward incidents (SUIs). Staff and patient surveys continually gave signs of dissatisfaction with the way the Trust was run, and yet no effective action was taken and the Board lacked an awareness of the reality of the care being provided to patients. The failure to respond to these warning signs indicating poor care could be due to inattention, but is more likely due to the lack of importance accorded to these sources of information.

Poor governance

1.10 The Board failed to get a grip on its accountability and governance structure throughout the period under review, despite these being issues that were apparent to the incoming Chair and Chief Executive in 2004 and 2005. The national general acceptance of the importance of clinical governance had failed to permeate sufficiently into Stafford to result in a functioning, effective system by 2009. The evidence fully supports the description of the Trust's clinical governance process throughout the period with which this Inquiry is concerned as "vestigial".[1] The absence of such a system meant that the leadership of the Trust was bound to be blind to many concerns which it took the HCC to uncover by its investigation.

1 CL0000003416 Counsel to the Inquiry's closing submissions, chapter 9, the Trust, para 100

Lack of focus on standards of service

1.11 It is clear from the evidence at both inquiries that the Trust was operating in an environment in which its leadership was expected to focus on financial issues, and there is little doubt that this is what it did. Sadly, it paid insufficient attention to the risks in relation to the quality of service delivery this entailed.

1.12 Throughout the period with which this Inquiry is concerned, the Trust suffered financial challenges. These pressures were regarded both inside and outside the Trust to be nothing particularly remarkable compared with other similar organisations, and therefore they were never treated as a particular cause for concern. However, I have no doubt that the economies imposed by the Trust Board, year after year, had a profound effect on the organisation's ability to deliver a safe and effective service.

Inadequate risk assessment of staff reduction

1.13 There was an unacceptable delay in addressing the issue of shortage of skilled nursing staff. There can be little doubt that the reason for the slow progress in the review, and the slowness of the Board to inject the necessary funds and a sense of real urgency into the process, was the priority given to ensuring that the Trust books were in order for the FT application. The result was both to deprive the hospital of a proper level of nursing staff and provide a healthier picture of the situation of the financial health of the Trust than the true reality, healthy finances being material in the achievement of FT status. While the system as a whole appeared to pay lip service to the need not to compromise services and their quality, it is remarkable how little attention was paid to the potential impact of proposed savings on quality and safety.

Nursing standards and performance

1.14 As a result of poor leadership and staffing policies, a completely inadequate standard of nursing was offered on some wards in Stafford. The complaints heard at both the first inquiry and this one testified not only to inadequate staffing levels, but poor leadership, recruitment and training. This led in turn to a declining professionalism and a tolerance of poor standards. Staff did report many incidents which occurred because of short staffing, exhibited poor morale in their responses to staff surveys, and received only ineffective representation of concerns from the RCN.

Wrong priorities

1.15 The Trust prioritised its finances and its FT application over its quality of care, and failed to put patients at the centre of its work.

1.16 The Board of the time must collectively bear responsibility for allowing the mismatch between the resources allocated and the needs of the services to be delivered to persist without

protest or warning of the consequences. However, they were able to fail in this way because of deficiencies in the system around them.

The voice of the local community

1.17 It is a significant part of the Stafford story that patients and relatives felt excluded from effective participation in the patients' care. The concept of patient and public involvement in health service provision starts and should be at its most effective at the front line.

1.18 Analysis of the patient surveys of the Trust conducted by the HCC and the Picker Institute shows that they contained disturbing indicators that all was not well from long before the intervention of the HCC.

1.19 Community Health Councils (CHCs) were almost invariably compared favourably in the evidence with the structures which succeeded them. It is now quite clear that what replaced them, two attempts at reorganisation in 10 years, failed to produce an improved voice for patients and the public, but achieved the opposite. The relatively representative and professional nature of CHCs was replaced by a system of small, virtually self-selected volunteer groups which were free to represent their own views without having to harvest and communicate the views of others. Neither of the systems which followed was likely to develop the means or the authority to provide an effective channel of communication through which the healthcare system could benefit from the enormous resource of patient and public experience waiting to be exploited.

1.20 Patient and Public Involvement Forums (PPIFs) relied on a variably effective, locally provided infrastructure. The system gave rise to an inherent conflict between the host, which was intended to provide a support service but in practice was required to lead with proposals and initiatives offered to lay members, and members of the forum, who were likely to have no prior relevant experience and to be qualified only by reason of previous contact with the hospital to be scrutinised.

1.21 In the case of the Trust's PPIF, the evidence shows quite clearly the failure of this form of patient and public involvement to achieve anything but mutual acrimony between members and between members and the host. A preoccupation with constitutional and procedural matters and a degree of diffidence towards the Trust prevented much progress.

1.22 If anything, local Involvement Networks (LINks) were an even greater failure. The, albeit unrealised, potential for consistency represented by the Commission for Patient and Public Involvement in Health (CPPIH) was removed, leaving each local authority to devise its own working arrangements. Not surprisingly, in Stafford the squabbling that had been such a feature of the previous system continued and no constructive work was achieved at all.

1.23 Thus, the public of Stafford were left with no effective voice – other than CURE – throughout the worst crisis any district general hospital in the NHS can ever have known.

1.24 Under the new reforms, local healthwatch is intended to be the local consumer voice with a key role in influencing local commissioning decisions through representation on the local Health and Well-being Board. They will be expected to build on existing LINks functions. The responsibility for establishing Local Healthwatch will rest with the local authorities in the same way as it had for LINks. As is the position with LINks, the DH does not intend to prescribe an operational model, leaving this to local discretion. It does not prejudice local involvement in the development and maintenance of the local healthcare system for there to be consistency throughout the country in the basic structure of the organisation designed to promote and provide the channel for local involvement. Without such a framework, there is a danger of repetition of the arguments which so debilitated Staffordshire LINks.

1.25 The local authority scrutiny committees did not detect or appreciate the significance of any signs suggesting serious deficiencies at the Trust. The evidence before the Inquiry exposed a number of weaknesses in the concept of scrutiny, which may mean that it will be an unreliable detector of concerns, however capable and conscientious committee members may be.

1.26 Local MPs received feedback and concerns about the Trust. However, these were largely just passed on to others without follow up or analysis of their cumulative implications. MPs are accountable to their electorate, but they are not necessarily experts in healthcare and are certainly not regulators. They might wish to consider how to increase their sensitivity with regard to the detection of local problems in healthcare.

1.27 There are a wide range of routes through which patients and the public can feed comments into health services and hold them to account. However, in the case of Stafford, these routes have been largely ineffective and received little support or guidance.

1.28 Local opinion is not most effectively collected, analysed and deployed by untrained members of the public without professional resources available to them, but the means used should always be informed by the needs of the public and patients. Most areas will have many health interest groups with a wealth of experience and expertise available to them, and it is necessary that any body seeking to collect and deploy local opinion should avail itself of, but not be led by, what groups offer.

General practitioners

1.29 The local GPs only expressed substantive concern about the quality of care at the Trust after the announcement of the HCC investigation, when it had become obvious there were issues and when they were specifically asked.

1.30 No individual or organisation can be singled out for criticism in this; they were not explicitly required to act in this way, and unfortunately it did not occur to any of them to suggest it. It will be important for the future that all GPs undertake a monitoring role on behalf of their patients who receive acute hospital and other specialist services. They have a role as an independent, professionally qualified check on the quality of service, in particular in relation to an assessment of outcomes. They need to have internal systems enabling them to be aware of patterns of concern, so that they do not merely treat each case on its individual merits. They have a responsibility to all their patients to keep themselves informed of the standard of service available at various providers in order to make patients' choice a reality. A GP's duty to a patient does not end on referral to hospital, but is a continuing relationship. They will need to take this continuing partnership with their patients seriously if they are to be successful commissioners of services. They should exploit to the full this new role in ensuring their patients get safe and effective care.

The Primary Care Trusts

1.31 PCTs were large organisations with substantial budgets and staff, particularly in comparison with SHAs. They were under a duty to monitor and improve the quality of the services they commissioned. They were over time provided with tools which in theory would have enabled them to lay down safety and quality standards, monitor performance, and pursue remedies on behalf of patients, individually and collectively, where those standards had not been met. In general, however, the nationally available guidance did not lend itself to more than relatively crude measures in this regard, the focus remaining, as elsewhere in the NHS system, on financial control and a handful of access targets. Development of more sophisticated tools, both locally and nationally, was slow, with the result that it is not in the least surprising that, in spite of the rhetoric of quality, one of the worst examples of bad quality service delivery imaginable was not detected by this system. There was a significant gap between the theory of the PCTs role and their capacity to deliver.

1.32 Throughout the period under review, the purchaser/commissioning arm of the system was subjected to constant reorganisation, usually taking place well before it had been possible to put fully into practice and embed the aspirations of the previous changes. The time and resources required to be devoted to reorganisation undoubtedly made it more difficult for PCTs to develop effective methods of imposing standard quality requirements and of effectively monitoring their delivery. Whilst the PCT cannot be criticised for the fact of reorganisation itself, it failed to put in place systems and processes to manage the inevitable risks that would occur as the new system established itself.

1.33 During this period, undue comfort was taken from the assumption that others had responsibility in terms of quality, and little if any attempt was made to collect quality information in a systematic way. Agreements with provider organisations were lacking in sophistication and the tools to enforce standards. It is not possible on the evidence before

this Inquiry to determine if the PCTs of the West Midlands were exceptional in this regard, but those who worked for them who gave evidence did not believe they were. If this is true, then there was a highly concerning gap in the system of oversight of safety and quality throughout the country.

1.34 South Staffordshire PCT (SSPCT) did monitor quality at the Trust with increasing intensity following the announcement of the HCC investigation. It did not rely entirely on an assumption that it had to await the outcome of the investigation. What was less satisfactory was the time taken to address issues and the difficulty experienced in using contractual solutions to expedite improvements. This was in part due to the dilemma faced by many commissioners in not wishing to exacerbate an already undesirable situation by destabilising the provider when there was no alternative available. There was also a willingness to accept that clinical safety was not compromised in spite of evidence which, if viewed from the perspective of a patient, should have suggested that it was. It should have been clear from the history and the nature of the deficiencies being reported, particularly in relation to staffing, that a dangerous situation had been allowed by the Trust leadership to develop and that urgent action and intervention were required.

1.35 The commissioning landscape has now changed, with the introduction of the national NHS Commissioning Board, its regional offices and clinical commissioning groups. However, the essential tenets required of the commissioning process may not have changed. The experience of Stafford shows an urgent need to rebalance and refocus commissioning into an exercise designed to procure fundamental and enhanced standards of service for patients as well as to identify the nature of the service to be provided. However, none of this will turn a theory of effective commissioning or monitoring into practice unless commissioners are recognisable public bodies, visibly acting on behalf of the public they serve and with a sufficient infrastructure of technical support. Effective local commissioning can only work with effective local monitoring. And that cannot be done without knowledgeable and skilled local personnel engaging with an informed public.

The Strategic Health Authorities

1.36 The role expected of SHAs was challenging. They were required to perform this throughout a time of extensive reorganisation, financial challenge, and reduction in staff and organisational resources. There also appears to have been a lack of clarity with regard to the extent to which SHAs were expected to address concerns about quality and safety.

1.37 The structural reorganisation of SHAs and their relationship with PCTs and providers in 2005/06 appears to have been conducted without any assessment of the risks to patient safety or the quality of service posed by the process of change. The reconfiguration of PCTs and development of the concept of commissioning meant that there was a serious lack of connection between the understandings of PCT leadership and of the SHA, and between

strategic overview and performance management. This increased the risks attached to mutual misunderstandings about where a function was being performed, and widened the gap through which poor performance could pass unnoticed. It does not seem to have been realised within the leadership of the West Midlands SHA (WMSHA), at that time, that these issues gave rise to a serious risk of compromises to patient safety going unnoticed or uncorrected.

1.38 There was also no system for ensuring the transfer of information and knowledge from one iteration of the SHA to the next, in spite of the very substantial staff cuts that accompanied the change.

1.39 In spite of these difficulties, few of which were of SaSSHA's or the WMSHA's own making, the evidence shows that the WMSHA did not explicitly relinquish an involvement in the performance management and oversight of provider trusts, but, on the contrary, was willing to intervene, forcefully if necessary. It did not proactively seek out quality and safety concerns, but it did seek to respond to concerns of which it became aware.

1.40 However, the WMSHA's handling of concerns raised in connection with the Trust often resulted in a collective judgement being made that there was nothing of concern warranting exceptional action. It took false comfort from the notion that some potential causes for concern were not exceptional in trusts under its oversight. This was due to an overall culture which was too ready to place trust in provider boards, was readier to defend providers than to consider the implications of criticisms and concerns being expressed, and was prepared to assume that others would share information showing concern and requiring action without being asked. In that sense, the WMSHA became far too remote from the patients it was there to serve, and it failed to be sufficiently sensitive to signs that patients might be at risk.

1.41 In relation to the Trust's application for FT status, the SHA did not offer information to the DH about a series of concerns arising in relation to the quality of services at the Trust, of which it was, or should have been, aware. Its approach, doubtless driven by the focus of the process as a whole on financial and corporate governance and not clinical standards, was to be supportive and focus on a goal of advancing the Trust as a successful applicant as an end in itself. This meant the SHA's focus was on financial and governance issues, as the key criteria valued by the DH and Monitor. However, the SHA should not have allowed itself to forget that the purpose of any development in the NHS should be to improve the ability of the system to care for its patients. There were Board to Board "challenge" meetings, but those gave insufficient consideration to whether the deficiences found in the planning process raised concerns about the general competence of the management of the Trust. The support of the SHA offered false reasurrance to the DH as to the soundness of the Trust as a potential applicant. No attempt appears to have been made to consult the HCC as the regulator or to inform it that the Trust was entering the FT "pipeline". No consideration was given to whether

the demands of the process of applying for FT status gave rise to any unacceptable risks for patients.

1.42 During the HCC investigation, although the SHA offered support to the Trust, it was not in a position to lead or direct performance management of the Trust as an FT and in any event it felt reluctant to do more, given the level of scrutiny to which the Trust was already being subjected. What it could have done was to have taken a more direct interest in the commissioning relationship via its oversight of the PCT. By whatever route, there was a need, in the interests of patients, for joint action by all those in a position to take it. While some steps were taken, the impression given has been one of waiting to see the outcome of the investigation rather than to accept that there was a current fundamental crisis giving rise to risks to patient care.

1.43 The underlying reason for the failure of SaSSHA and the WMSHA to adequately seek out or address patient safety and quality concerns about service provision at the Trust, was a failure of the leadership to give sufficient explicit priority to the protection of patients and to ensuring that patient safety and quality standards were being observed there. In common with the system as a whole at the time, the focus was unduly directed at financial and organisational issues and an over reliance on assurances given by others, while losing sight of the central purpose of the service it was seeking to support.

1.44 The analysis of the evidence shows that important opportunities to detect and act upon the serious systemic failings in the Trust were missed because no one at the WMSHA seems to have realised or appreciated the significance of the issues.

1.45 A proper and reasonable strategic direction taken by the WMSHA was the attempt to develop metrics focused on patient safety. However, this initiative not only took a long time to complete, it was watered down by replacing the idea of outcome-based measures with more indirect ones. The WMSHA recognised, correctly, that there was a gap in safety monitoring that required a means of measuring safety. However, at a time when the metrics were not ready to be implemented and incorporated into contracts and PCTs had few, if any, other tools available to them to undertake their own monitoring, the SHA gave insufficient consideration to the implications of this delay in developing its own metrics for the performance of its duties.

1.46 The WMSHA has pointed out to the Inquiry that the Trust was but one of many organisations in the region with problems, and the WMSHA was relatively small and had a lot to cope with. This again is not an excuse for inaction. Either the SHA had the resources and ability to do the entire job which had been delegated to it, and it failed to carry out that job, or it did not have the resources and ability and failed to alert those responsible to the problem.

1.47 It may be thought that an analysis of the faults of an SHA is now redundant, as they are now being abolished. This could not be further from the truth. Whatever the changes made under the recent reforms, or which might be made in the future to the structure of the NHS, a performance management and strategic oversight function will reside somewhere in the system.

Monitor and the failure of the foundation trust authorisation process and oversight

1.48 It is fair to point out that even if Monitor had refused FT status to the Trust this would not have avoided much of the suffering endured by so many patients before January 2008. The deficiencies which have come to light at the Trust subsequently are not attributable to FT status as such. However, there is no doubt that an elaborate regulatory assessment process of the nature required by the National Health Service Act 2006 ought to have brought those deficiencies to light, and its failure to do so calls into question the effectiveness of the FT regulatory system as a whole. While the Inquiry has been warned, rightly, of the dangers of extrapolating from an extreme case, it has to be questioned whether the system could reliably detect concerns relevant to patients of any significant nature, if it could not detect a case as gross as that of the Trust.

1.49 The application process provided an opportunity for a comprehensive investigation of an applicant's capability and capacity to deliver a consistent and sustainable service to its patients which was safe, effective and compliant with minimum safety and quality standards. It was clearly not intended that a trust suffering from a systemic failure to provide such a service should be authorised as an autonomous entity, thus removing it from the Secretary of State's sphere of accountability and control.

1.50 It is clear from the evidence that the Trust would not have been in a position to be authorised as an FT in early 2008 if:

- The eligibility criteria had not been loosened;
- A thorough assessment of the Trust's compliance with minimum patient safety and quality standards had been performed, rather than the focus of Monitor's assessment being on finance and corporate governance;
- The DH applications committee had been unwilling to support marginal cases;
- The Minister had been offered a full picture of the Trust when considering giving his support;
- Monitor had not relied on, but had probed more deeply, the Trust's assurances on quality issues;

- Monitor and the HCC had communicated with each other and shared their knowledge.

1.51 In short, an elaborate, resource-consuming process failed to achieve what should have been its primary objective; ensuring that the only organisations authorised were those with the ability and capacity to deliver services compliant with minimum standards on a consistent and sustainable basis.

1.52 The erroneous authorisation of the Trust as an FT came about almost entirely because the HCC and Monitor were separate organisations, going about their regulatory business without coordinating their activities with each other. This was not just a matter of communication but of different, unaligned methods of assessment. Thus, no effective consideration was given to the potential effects of cost savings and staff cuts on patient safety and quality. The HCC had little by way of financial expertise available to it, and Monitor, likewise, little clinical resource. The impact of one on the other does not seem to have been fully appreciated.

1.53 This communication failure may in part have been as a result of Monitor fiercely guarding its independence, at the expense of fostering good relationships with others.

1.54 Monitor did not formally decide that the Trust was in significant breach of its authorisation until after the publication of the HCC report. However, it had been aware since at least May 2008 that there was a likelihood that it was in significant breach. Even before then, there were substantial grounds for suspecting that there was a continuing breach. Monitor did, in the event, take some action before the publication of the report, when it became clear to it that the position of the Chair, and, in reality, the Chief Executive as well, were untenable.

1.55 The reason no intervention took place earlier was the view of Monitor's senior management that it should wait for the HCC's final report or for it to make interim recommendations for intervention. It did so because it took the view that, until either of those conditions were fulfilled, it lacked the evidence on which to proceed.

1.56 The evidence shows that the reasoning adopted was flawed. The constant complaint to the HCC that the investigation was taking too long arose out of Monitor's concern that regulatory action was required. It could have, but did not, request the HCC to furnish it with an interim report presenting the evidence and any recommendations that Monitor believed to be lacking. In any event, it was wrong to believe there was insufficient evidence to act. It had evidence that the HCC had concluded that there was a sufficient threat to safety to require the Trust to take immediate action. It became over-preoccupied with a distinction between evidence and information, while failing to give sufficient regard to its duty to protect patients.

1.57 The result of this hesitation to act was that the Trust continued, for a sustained period, to have a leadership which was deficient and unable to command confidence, in circumstances where there were serious and widespread deficiencies relevant to patient safety, of which both systems regulators were aware. During that period, while individual concerns were beginning to be addressed, fundamental issues remained. Put shortly, the public remained exposed to an unacceptable level of risk. While it can be said that the HCC could have made express recommendations to Monitor for action, Monitor retained its own statutory responsibility and judgement, as well as the power of intervention. Insofar as it exercised these, it did so with undue delay.

The Healthcare Commission

1.58 The system of regulation which the HCC was given to run failed to prevent or detect over three-quarters of its lifetime what has been described as the biggest scandal in NHS history. At the same time, it was the first organisation out of the plethora with relevant responsibilities to identify serious cause for concern, and to take the action which led to the full exposure of the scandal. This success was due to an eventual willingness to take the only action available to establish the true level of concern, namely a thorough and challenging investigation of the true facts on the ground.

1.59 At the heart of the failure to detect or prevent the appalling events at Stafford sooner was the concept of the core standards and the means of assessing compliance: the annual health check (AHC). The core standards suffered from a number of deficiencies.

1.60 Generic standards were formulated not by the regulator but by the Government, thereby inhibiting the engagement with the standards of those working in the system and therefore the effectiveness of the regulator. While there was a consultation period and the manner of assessing compliance was left to the HCC, the fact is that the standards were formulated and handed down by the DH. This must have contributed to the impression that the process was Government controlled and thereby reinforced the disengagement of frontline clinicians from a concept, which if it was to work, demanded their involvement and endorsement.

1.61 A further difficulty was that the standards included a confusing mixture of the general and the specific: minimum standards and aspirations. They were expected to do too much: to set a minimum below which no provider should fall, to include targets in areas of particular interest to Government and to be a basis for comparison of providers to assist the public in making choices.

1.62 The assessment process also suffered a number of defects. Principal among them was the reliance on self-assessment and self-declaration as the basis of regulation. The checks put in place by the HCC to verify self-declarations were inevitably a net with a wide mesh through which inaccurate self-assessment and deficiencies in practice could pass undetected. The focus

was on examining providers' apparent performance in relation to standards, most of which focused on the presence of theoretical systems, not on real achievements and outcomes for patients. Many of these issues revealed the HCC's willingness to accept assurances of action from the Trust at face value. Regulation cannot be effective if it does not challenge claims of compliance made by the regulated organisations, and its prime purpose in protecting patients cannot be served by such a passive approach. It would be easy to offer criticism of individuals in relation to the failure to investigate more intrusively, but the fault lay in the inadequacy of the systems in place to pursue a potentially serious concern effectively.

1.63 It was perhaps inevitable that, in the first instance, the new concept of setting national standards would remain under the close control of Government: the move to setting standards at all was a progressive development designed to promote the protection of patients and improvement to the service. However, the experience of such an approach reveals a need for a more transparent standard-setting process – one whose requirements are understood and accepted by patients, the public and the staff who apply them. This would leave responsibility for improvement to the commissioning system for which, ultimately, the Government can be held to account via its use of the NHS Commissioning Board "mandate".

1.64 While a close relationship with the DH was inevitable, the way in which the standards to be applied were handed down might at least have given the appearance of compromising its independence. To this day, the boards of regulators are hired and fired by the Secretary of State. Professor Sir Ian Kennedy had recommended in his Bristol Inquiry report that the regulator be independent of the DH. In practice, there appear to have been constraints on the extent of its independence which were not helpful to the performance of its role.

1.65 It is clear that the AHC was not a satisfactory means of establishing whether the Trust or any other provider was complying with satisfactory standards of care, but this was not the only means by which the safety and quality of the Trust's service could be assessed, and there were warning signs which could have triggered a greater level of concern sooner. This included complaints about hygiene and concerns about appraisals in 2006, the Trust's handling of the Children's Services Review and concerns about resuscitation equipment in 2006, inconsistencies between the AHC self-declaration and other information, and the hygiene code inspection in 2007. Taken cumulatively, these areas of concern should have triggered an earlier regulatory response and more proactive intervention than in fact occurred. It has been suggested that the failure to take action might have been the result of "regulatory capture" of the HCC's regional team, but it is more likely that the cause was the system which discouraged intervention and required information to be filed centrally, where insufficient weight was allowed to be given to individual items which, when examined, were in themselves cause for concern – all this was against a background which placed considerable reliance on assurances from trusts as to remedial action.

1.66 The period under review in this Inquiry was one of transition from one end of the spectrum to the other. Having set up a new system of regulation under the HCC, which for all its faults was an advance on what went before, the demands of embedding and developing new concepts were compounded by a decision to abolish it wholesale before it had really got going. Inevitably, this slowed the development process while resources and attention were devoted to the running down of one organisation and the setting up of yet another.

1.67 Communication of intelligence between regulators needs to go further than sharing existing concerns identified as risks, and it should extend to all intelligence which when pieced together with that possessed by partner organisations may raise the level of concern. Too many assumptions were made that others would be aware of important information.

1.68 The HCC was subjected to a great deal of pressure from Monitor and the WMSHA about the length of time taken for the investigation to report. This criticism was and remains ill-founded. It is quite clear that Dr Heather Wood from the HCC and her team found an unprecedented range of issues suggestive of serious concerns. If they had acted as suggested, it is highly unlikely that the full breadth and gravity of the issues would have been brought to light. The HCC was absolutely right to insist on undertaking a thorough and searching investigation and to take the time necessary to do that.

1.69 When the information coming into the HCC's possession during the investigation is looked at sequentially it is clear that a situation was being uncovered in which patient safety was not being properly ensured. It is often not practical to take steps to close a service, let alone a whole hospital, but it is unacceptable to find deficiencies of the nature described in Dr Wood's letters and, while leaving the public in ignorance of those findings, to continue relying on the assurances of the provider's management that they are taking action. At the very least, some form of external performance management presence was required at the Trust to oversee interim arrangements for protecting the public. The system at the time did not allow the HCC to take that sort of action, and the culture did not encourage it to advise other organisations how to do their jobs. It is therefore not surprising that neither the investigation team nor the higher echelons of the organisation was thinking in those terms. If there is a criticism to be made, it is that they did not spell out with sufficient clarity the safety implications of the findings in terms of the increased level of risk presented to patients.

1.70 What was undoubtedly a success was the achievement of the formal investigation to root out the full extent of the appalling problems at the Trust. If criticism can be made of some of the detail of how the investigation was carried out, there is no doubt that without what was done many more patients would have had to suffer before any effective action was taken. The investigation demonstrates how powerful the combination of direct observation of practice, contact with patients, families, frontline staff and examination of real cases is, as opposed to reliance on files of policies, committee minutes and overall figures. This is not to say that examination of systems is not important, but it is not and never will be sufficient.

Care Quality Commission

1.71 The general theory of the new regulatory model is encouraging: it depends on the collection of a wide range of information which is used to identify a level of risk of non-compliance, which informs decisions on what organisations to target for review.

1.72 However, the CQC has had many challenges since its inception, including the need to merge three organisations, the creation and administration of an entirely new system of registration and the monitoring of compliance with a new set of standards. Added to the challenge has been the requirement to take on the regulation of other healthcare sectors. All this has had to be achieved within a short timescale. There can be no one correct way to have set about this task and it was inevitable that changes of strategic direction will have been necessary to react to growing experience. The evidence does, however, give the impression that strategy has to some extent been driven by a perceived need to fit the activity of the organisation to the resources available.

1.73 These pressures have, perhaps predictably, led to it being less than easy to fulfil the basic task that the CQC is charged with, namely protecting patients from substandard care, and the provision of accurate information on which the public and others can rely to make decisions.

1.74 The evidence received by this Inquiry does not suggest that the CQC is a happy environment to work in. The massive upheaval that has taken place in its creation has led at least some elements of staff, from the frontline to the Board, to express concerns and to believe they have not received an adequate response. While it is clear that the CQC aspires to be an organisation which welcomes constructive comment, the Inquiry has seen evidence of a defensive institutional instinct to attack those who criticise it, however honestly and reasonably those criticisms are made. A healthcare regulator needs to be a model of openness and therefore welcome constructive criticism.

1.75 The current structure of standards, laid down in regulation, interpreted by categorisation and development in guidance, and measured by the judgement of a regulator, is clearly an improvement on what has gone before, but it requires improvement.

1.76 While a tremendous amount of work has obviously gone into matching the outcomes in the essential standards with the regulations, there is a lack of clarity which derives from the regulations combining in one regulatory requirement a number of different concepts, such as "safety" and "welfare." They are requirements which have to be met, but are not necessarily given very much attention as statutory obligations, in day-to-day clinical work.

1.77 The standards to be enforced by the regulator should be a clear fundamental set of standards, driven by the interests of patients, and devised by clinicians; a "bottom up" as opposed to a "top down" system. Unfortunately, for all its good intentions and its improvement on what

went before, the current outcomes are over-bureaucratic and fail to separate clearly what is absolutely essential from that which is merely desirable.

1.78 The sense to be gained from the evidence before the Inquiry is that there has been a change of direction from an emphasis on planned, routine reviews, to more focused responsive reviews triggered by concerns. In addition, a substantial series of inspections have been carried out at the direction of the Secretary of State. It is clear on the other hand that the CQC intends to maximise the ability to make decisions based on a comprehensive database of risk information relevant to the assessment of risk.

1.79 The need for risk-based reviews or inspections is recognised by the CQC, and it appears that an increasing amount of inspectors' time is taken up with them. That inevitably causes a challenge in relation to the performance of planned or routine reviews of organisations which have not shown an increased level of risk on the quality and risk profile (QRP). The story of Stafford shows the importance of not ignoring trusts which have failed to appear on the radar of concern.

1.80 While the CQC is to be commended for its efforts, the impression is that patient information and feedback are not priorities as a means to obtaining relevant information about an organisation or generally when the CQC is considering its regulatory approach. It is service users, including visitors and families, who are likely to be the first to witness poor outcomes or the warning signs that standards are slipping. It is here that a more specific focus by local inspectors on complaints, allowing perhaps for contact with complainants, would be of great assistance.

Professional regulation

The General Medical Council and the Nursing and Midwifery Council

1.81 The story of Stafford shows that the conduct of individual doctors and nurses can be relevant to the analysis of the failure of an organisation to perform its duty to its patients. Currently, such cases, where they come to light, are dealt with by the relevant professional regulator as if in a silo, applying a differently worded code of conduct, a different approach to sanctions, and by reason of the matters being dealt with in different systems, the possibility of inconsistent outcomes.

1.82 The General Medical Council (GMC) and the Nursing and Midwifery Council (NMC) have faced similar challenges in regulating the role of healthcare professionals at the Trust, with the absence of referrals from professionals. This may well have been due to the unhealthy culture described in the first inquiry report. The lack of complaints from the public may well have been due to the lack of profile each organisation has. Both the public and professionals may also be deterred from referring cases by the apparent complexity of the process and the time taken to resolve cases.

1.83 Where referral is absent, as was the case at the Trust, then other means are necessary to ensure that the public is protected. Both organisations need to develop their capacity to examine and investigate concerns even where no named individual has been identified to them. However, at the moment, the impression is that neither the GMC nor the NMC has the capacity or skills to undertake this sort of work.

Deanery/universities

1.84 The system of regulation and oversight of medical training and education in place between 2005 and 2009 failed to detect any concerns about the Trust other than matters regarded as of no exceptional significance. There were a number of factors contributing to this:

- While patient safety was theoretically given primacy in the system, the domain to be monitored was unduly limited to the potential risk posed to patients by the trainee.
- Insufficient consideration was given to the relevance of good quality training of practice in a setting which complied with minimum patient safety and quality standards, and to the professional obligation to protect patients from harm.
- The Postgraduate Medical Education and Training Board (PMETB)/GMC/deanery wide reviews focused on deanery systems of quality management, resulting in only superficial examination of the standards being observed. Such reviews did not consistently consider compliance with patient safety standards.
- When concerns were raised about inappropriate pressure or bullying by staff towards trainees these were not followed up or investigated.
- Systematic communication of indications of serious concern, such as the HCC investigation, was almost completely lacking between the regulators, and between them and the deanery.
- A reluctance to prejudice the provision of a service or the training of trainees has resulted in the implied threat of removal of approval for providing training places being largely theoretical.

1.85 While requirements for remedial action must be proportionate, training should not be allowed to take place in an environment where patient safety is not being adequately protected. Perceived difficult consequences should never be permitted to hinder steps required to protect patients, and the oversight of medical training should not condone or support unacceptable practice. As elsewhere in the system, a sense of urgency may have been lacking, even after the scale of the deficiencies at the Trust had become apparent.

1.86 All doctors, whether fully qualified or in training, work in environments where they are under a duty to protect patients. Good practical training should only be given where there is good clinical care. Absence of care to that standard will mean that training is deficient. Therefore, there is an inextricable link between the two that no organisation responsible for the provision, supervision or regulation of education can properly ignore. Trainees are invaluable eyes and ears in a hospital setting.

Others

Health Protection Agency

1.87 The Health Protection Agency's (HPA's) involvement with trusts and often intimate knowledge of their systems for controlling healthcare associated infections (HCAIs) mean that it will often come into possession of information which could be of value to those responsible for oversight of the healthcare system, including the quality regulator.

1.88 The HPA did not escalate its concerns about infection control at the Trust promptly to the HCC or the SHA. It did not volunteer information to the HCC despite its knowledge that an investigation was being undertaken. It did not have any contact with Monitor in relation to the Trust, despite the Trust's FT status from February 2008.

1.89 There was insufficient consideration given to the importance of communication with regulatory and supervisory bodies in order to ensure that relevant information pertinent to patient safety was properly disseminated, discussed and appropriate action considered. There has, therefore, been a concerning absence of proactive sharing of information or consideration of how this should be arranged. Organisational boundaries and cultures should not prevent the use by all of information and advice designed to enhance patient safety.

The Health and Safety Executive

1.90 The Health and Safety Executive (HSE) has responsibilities over virtually every form of workplace and activity, and the scope of its activity is extremely wide. Therefore, the HSE has devised a policy seeking to define the factors on which its discretion to involve itself or not in healthcare will be based. Inevitably, it is not possible for a full investigation, still less a prosecution, to be brought in every case where there has been a possible breach of the Health and Safety at Work Act 1974 or the regulations made under it.

1.91 However, while it is always going to be difficult to devise policies which will satisfy the many conflicting requirements of the public interest, it is clear that the principles by which the HSE has sought to decide whether or not to involve itself in healthcare cases has led to a particularly unsatisfactory situation when placed alongside the CQC's refusal to investigate individual cases. This has led to a regulatory gap which needs to be closed.

1.92 Given the current gap through which serious cases of safety breaches in a healthcare setting are likely to fall, the approach of the HSE is not calculated to maintain public confidence. The approach has the appearance of looking for reasons for not taking action rather than starting from a consideration of what is in the public interest. A concentration on the effect of a decision on resources has led to the unacceptable position that the more serious and widespread a failure is, the less likely it is that HSE will decide to intervene.

1.93 A perceived lack of expertise within the HSE is not regarded in other spheres as a reason for it not to investigate a case otherwise requiring it. The answer is of course to obtain external and independent expert advice, as is done day in and day out in the field of healthcare litigation and fitness to practise proceedings.

1.94 This regulatory gap needs to be closed. It should be recognised that there are cases which are so serious that criminal sanction is required, even where the facts fall short of establishing a charge of individual or corporate manslaughter. The argument that the existence of a criminal sanction inhibits candour and cooperation is not persuasive. Such sanctions have not prevented improvements in other fields of activity.

1.95 The HSE has faced difficulties and dilemmas in applying its very broad jurisdiction to healthcare. There has been a gap between what the HSE and the CQC are respectively able or willing to regulate. This has caused distress to patients and those close to them who seek redress for safety breaches. Either the CQC should be given power to exercise the statutory health and safety functions in respect of regulated organisations, or a new comparable offence should be created in respect of which the CQC has power of prosecution.

National Patient Safety Agency

1.96 Patient safety information, in the form of incident reports, is a vital part of what is required for patient protection, and the development of a system to collect such information nationally is welcome. The National Patient Safety Agency (NPSA), up to its abolition in June 2012, sought to master a challenging field, and made considerable progress. However, further development is still required, as the existing system played no part in the uncovering of the lack of safety at the Trust.

1.97 These very positive developments have taken a long time to implement, due in part to the challenges thrown up by the many structural reorganisations of the NHS during the period in question, and the relatively low priority accorded to this area of activity as a result.

Royal College of Nursing

1.98 At Stafford, the RCN was ineffective both as a professional representative organisation and as a trade union. Little was done to uphold professional standards among nursing staff or to address concerns and problems being faced by its members.

1.99 A prime reason for this was the lack of effective representation from elected officers on site. Further, the support available from RCN officials at a regional and national level was limited.

1.100 The RCN is not, of course, a regulator but a combination of a professional representative body and a trade union. However, it does represent a group of qualified professionals and seeks, as it should, to promote high standards of service and conduct. The evidence reviewed in this report suggests that the RCN has not been heard as might have been expected in pursuing professional concerns about the standard of care.

1.101 It appears there is a concerning potential for conflict between the RCN's professional role of promoting high quality standards in nursing, and its union role of negotiating terms and conditions and defending members' material and other narrow interests.

Department of Health

1.102 The senior officials in the DH have accepted it has responsibility for the stewardship of the NHS and in that sense that it bears some responsibility for the failure of the healthcare system to detect and prevent the deficiencies at Mid Staffordshire sooner than it did. There is no doubt about the authenticity of their expressions of shock at the appalling story that has emerged from Mid Staffordshire. However, it is not possible to avoid the impression that it lacks a sufficient unifying theme and direction, with regard to patient safety, to move forward from this point in spite of the recent reforms put in place by the current Government.

1.103 The structural reorganisations examined during the course of the Inquiry tend to suggest that many policy changes over the period of review, put forward with the intention of improving the standards of the health service, were not given time to succeed before the next wave of reorganisation occurred. The former Secretary of State for Health, the Rt Hon Andy Burnham MP, accepted that there was often a disconnect between the policy decisions being made and their practical implementation.

1.104 Where there are perceived deficiencies, it is tempting to change the system rather than to analyse what needs to change, whether it be leadership, personnel, a definition of standards or, most importantly, culture. System or structural change is not only destabilising but it can be counterproductive in giving the appearance of addressing concerns rapidly while in fact doing nothing about the really difficult issues which will require long-term consistent management. While the DH asserted the importance of quality of care and patient safety in its documentation and its policies, it failed to recognise that the structural reorganisations imposed upon trusts, PCTs and SHAs implementing such policy have on occasion made such a focus very difficult in practice.

1.105 The Trust was criticised in the first inquiry report for not undertaking sufficient impact or risk assessments before making significant changes. The same also appears to be the case at a system-wide level.

1.106 Nevertheless, it is to the credit of successive Governments and the DH that they have over the last decade or so recognised the importance of setting standards for the delivery of healthcare rather than merely trusting organisations and professionals to deliver an acceptable service and assuming that regulation of individual professionals was a sufficient guarantee. However, the development of a structure that is effective has been very difficult, and it is clear that the journey is not yet complete.

1.107 The story of the development of standards within the healthcare system has been one of struggle between the rhetoric of improvement and the need for clarity about what is unacceptable.

1.108 The reality is that it is not the setting of national standards in itself which will "catch" a Mid Staffordshire but having effective methods of policing those standards. It is important that such policing is not confined to one method applied by a single organisation, but is undertaken in as many different ways as possible, through provider internal leadership, external but local public scrutiny, commissioning, and the regulator all working to a common set of values, standards and priorities. The DH has struggled to get the balance right between "light touch" regulation and the need to protect service users from harm.

1.109 In addition, despite the DH possessing highly impressive senior clinical figures, all of whom are clearly dedicated to making the NHS work for the people it serves, there is an impression that senior clinicians were not at the heart of decision-making on several key issues that have been examined at this Inquiry. Although a focus on quality has developed significantly in the last 10 years, the DH has failed to place it firmly at the core of its policy by assessing the impact of key policies, such as financial rebalance, the FT agenda and structural reform on quality. The DH should ensure that there is senior clinical involvement in all decisions which may impact on patient safety and well-being.

1.110 Some of the evidence the Inquiry has heard shows that DH officials are at times too remote from the reality of the service they oversee. They need to connect to its patients and frontline staff more personally and directly. Nothing is more likely to focus the mind on the impact of decisions on patients than to listen to patients' experiences. The most important cultural change should be to require all who work there to place the patient perspective at the forefront of their minds and deliberations in all they do. Evidence has shown that the DH has not always put patients first, prioritising other policies over patient considerations.

1.111 In considering the DH as a cultural leader, the evidence before the Inquiry does not justify a conclusion that there is in fact a culture within the Department which could properly be described as one of bullying. What the evidence does establish is that well-intentioned decisions and directives emanating from the DH have either been interpreted further down the hierarchy as bullying, or resulted in them being applied locally in an oppressive manner. It is not the intent that is in question, but the unintended consequences and perceptions of others as a reaction to DH requirements. There needs to be a careful balance between avoiding tolerance of unacceptable standards of performance and incentivising short cuts to compliance by applying career-threatening pressure to uphold such standards. The DH must ensure that performance requirements are balanced by provision of qualifications to allow patient safety and well-being to remain the priority, resources and support which enable the requirements to be met, and the restriction of suggestions of adverse career consequences to cases of misconduct or serious incompetence.

1.112 It is a truism that organisational culture is informed by the nature of its leadership. The DH has an important leadership role to play in promoting the change of culture required throughout the healthcare system.

1.113 The very complexity and size of the NHS presents challenges in creating and maintaining a positive patient-focused culture throughout. This challenge will increase as the autonomy of frontline organisations increases and each becomes more susceptible to the vagaries of local leadership. The DH has primary responsibility for providing the means for developing a consistent culture.

Why things were not discovered sooner

1.114 A primary purpose of this Inquiry is "to examine why problems at the Trust were not identified sooner; and appropriate action taken." This report identifies common themes that, when combined, led to the devastating state of affairs eventually discovered at the Trust:

- As identified during the first inquiry, the Trust was an organisation that lacked insight and awareness of the reality of the care being provided to patients. It was generally defensive in its reaction to criticism and lacked openness with patients, the public and external agencies.

- The responsibilities and accountabilities of external agencies were not well defined, often resulting in "regulatory gaps" or failure to follow up warning signs. Organisations operated in silos, without consideration about the wider implications of their role, even guarding their territories on occasion.

- This situation was exacerbated by a lack of effective communication across the healthcare system in sharing information and concerns. Organisations relied on others to keep them

informed rather than actively seeking and sharing intelligence. At the heart of the failure was a lack of openness, transparency and candour in the information emanating from the Trust and over-reliance on that information by others.

- This was not helped by the constant reorganisation of NHS structures, often leading to a loss of corporate memory and misunderstandings about an organisation's functions and responsibilities. Information flow was generally poor.

- The combination of these "regulatory gaps", lack of effective communication and constant reorganisation led to a systemic culture where organisations took inappropriate comfort from assurances given either by the Trust itself or from action taken by other regulatory organisations. As a result, organisations often failed to carry out sufficient scrutiny of information, instead treating these assurances as fulfilling their own, independent obligations.

- This culture of assurances was operating in a structure where identifying systems and processes and meeting targets were the main measures of performance. Outcomes-based performance and risk-based, intelligence-informed regulation were still developing concepts.

- The focus of the system resulted in a number of organisations failing to place quality of care and patients at the heart of their work. Finances and targets were often given priority without considering the impact on the quality of care. This was not helped by a general lack of effective engagement with patients and the public, and failure to place clinicians and other healthcare professionals at the heart of decision-making. Complaints were not given a high enough priority in identifying issues and learning lessons. Patients, clinicians and the public need to be at the heart of the health service and the decisions being made.

1.115 Each of these common themes is examined in detail throughout the main report.

Lessons learned and related key recommendations

A common culture made real throughout the system

1.116 The negative aspects of culture in the system were identified as including:

- A lack of openness to criticism;
- A lack of consideration for patients;
- Defensiveness;

- Looking inwards not outwards;
- Secrecy;
- Misplaced assumptions about the judgements and actions of others;
- An acceptance of poor standards;
- A failure to put the patient first in everything that is done.

1.117 It cannot be suggested that all these characteristics are present everywhere in the system all of the time, far from it, but their existence anywhere means that there is an insufficiently shared positive culture.

1.118 To change that, there needs to be a relentless focus on the patient's interests and the obligation to keep patients safe and protected from substandard care. This means that the patient must be first in everything that is done: there must be no tolerance of substandard care; frontline staff must be empowered with responsibility and freedom to act in this way under strong and stable leadership in stable organisations.

1.119 To achieve this does not require radical reorganisation but re-emphasis of what is truly important:

- Emphasis on and commitment to common values throughout the system by all within it;
- Readily accessible fundamental standards and means of compliance;
- No tolerance of non compliance and the rigorous policing of fundamental standards;
- Openness, transparency and candour in all the system's business;
- Strong leadership in nursing and other professional values;
- Strong support for leadership roles;
- A level playing field for accountability;
- Information accessible and useable by all allowing effective comparison of performance by individuals, services and organisation.

1.120 By bringing all this together, all who work to provide patient care, from porters and cleaners to the Secretary of State, will be working effectively in partnership in a common and positive culture.

Common values: putting the patient first – the NHS Constitution

1.121 The common values of the service must be enshrined in and effectively communicated by the NHS Constitution and owned and lived by all members of the service. The NHS Constitution should be the first reference point for all NHS patients and staff and should set out the system's values, and the rights, obligations and expectations of patients.

1.122 Patients must be the first priority in all of what the NHS does by ensuring that, within available resources, they receive effective care from caring, compassionate and committed staff, working within a common culture, and protected from avoidable harm and any deprivation of their basic rights.

1.123 The overarching value and principle of the NHS Constitution should be that patients are put first, and everything done by the NHS and everyone associated with it should be informed by this ethos.

1.124 The Constitution should incorporate reference to all codes of conduct and standards with which staff are expected to comply. All need to recognise their duty to contribute to the formulation of standard procedures facilitating compliance with required standards.

Standards

1.125 Enshrined in the NHS Constitution and systems regulations should be a commitment to abide by an integrated hierarchy of standards:

- Fundamental standards, which need to be applied by all those who work and serve in the healthcare system. Behaviour at all levels and service provision need to be in accordance with at least these fundamental standards. No provider should provide any service that does not comply with these fundamental standards, in relation to which there should be zero tolerance of breaches.
- Enhanced quality standards, which set requirements over and above the fundamental standards, which are a matter for definition and enforcement by the commissioners of services.
- Developmental standards setting longer term goals devised by commissioners and providers.

Simplifying regulation

1.126 In the case of Mid Staffordshire, the regulatory regime that allowed for overlap of functions led to a tendency for regulators to assume that the identification and resolution of non-

compliance was the responsibility of someone else. Effective accountability to the public demands a simpler regime of regulation.

1.127 Important information about the Trust did not pass from one organisation to another, leading to an erroneous decision about FT authorisation being made. The assessment of risk to patients would be more effective if the direct monitoring of compliance with fundamental standards and the monitoring of the organisation's ability to deliver compliance were the responsibility of one organisation. Such a change should not be seen as a reason to reduce the resources available for these tasks, and the merger of the functions should be undertaken incrementally and after thorough planning. The responsibility for the FT authorisation process should also be transferred. There is no logical case to have these issues dealt with by different bodies. The single regulator should deal with issues of patient safety, adherence to fundamental standards, corporate governance and financial competence and viability.

1.128 The Secretary of State should therefore consider transferring the functions of regulating governance of healthcare providers and fitness of persons to be directors, governors or equivalent persons (as dealt with elsewhere in the recommendations) from Monitor to the CQC. Merging of functions should not be undertaken with undue haste and without adequate planning to ensure that the corporate memory of Monitor is not lost. The merger should not be used as a justification for making cost savings in a way that would result in the merged body being under-resourced to undertake the required tasks.

Monitoring of compliance with fundamental standards

1.129 The fundamental standards should be policed by a single regulator, the CQC, monitoring both compliance with fundamental standards, and the governance and financial sustainability which will enable a provider to deliver compliant services on a sustainable basis. It should not be the role of the CQC to ensure improvement by the provider, but rather to ensure that compliance with the fundamental standards is such as to protect the safety of patients and the quality of the service provided.

1.130 The fundamental standards should be set out in a clear manner so they can be understood and accepted by providers, patients and the public. Whilst they will require Government approval, as they should be incorporated as regulations, they should not be imposed as "top down" standards but should be the subject of extensive consultation, particularly to ensure that patients, doctors and nurses have full confidence in them.

1.131 Compliance with the fundamental standards should be policed by reference to developing the CQC's outcomes into a specification of indicators and metrics by which it intends to monitor compliance. These indicators should, where possible, be produced by the National Institute for Health and Clinical Excellence (NICE) in the form of evidence-based procedures and practice

which provide a practical means of compliance and of measuring compliance with fundamental standards.

1.132 The procedures and metrics produced by NICE should include evidence-based tools for establishing the staffing needs of each service. These measures need to be readily understood and accepted by the public and healthcare professionals.

1.133 Adoption of these practices, or at least their equivalent, is likely to help ensure patients' safety. Where NICE is unable to produce relevant procedures, metrics or guidance, assistance could be sought and commissioned from the Royal Colleges or other third-party organisations, as felt appropriate by the CQC, in establishing these procedures and practices to assist compliance with the fundamental standards.

Enforcement of compliance with fundamental standards

1.134 Any service or part of a service that does not consistently fulfil the relevant fundamental standards should not be permitted to continue, and the CQC as regulator should have the ability to take immediate protective steps in the interest of patients' safety if it has concerns on the issue, even whilst considering or investigating the extent of non-compliance.

1.135 Non-compliance with a fundamental standard leading to death or serious harm of a patient should be capable of being prosecuted as a criminal offence, unless the provider or individual concerned can show that it was not reasonably practical to avoid this. Reliance might be placed for that purpose on effective implementation of the procedures devised by NICE, but this would offer no defence to those who had not followed such a procedure.

1.136 Information needs to be used effectively by regulators and other stakeholders in the system wherever possible by use of shared databases. Regulators should ensure that they use the valuable information contained in complaints and many other sources. The CQC's quality risk profile is a valuable tool, but it is not a substitute for active regulatory oversight by inspectors, and is not intended to be.

1.137 Inspection should remain the central method for monitoring compliance with fundamental standards. A specialist cadre of hospital inspectors should be established, and consideration needs to be given to collaborative inspections with other agencies and a greater exploitation of peer review techniques.

Applying for foundation trust status

1.138 It is recognised that the functions of Monitor will continue whilst the implementation of a recommendation to merge functions with the CQC is deliberated. The following recommendations apply to the manner of application for FT status whether prior to, or after,

the merger. For these purposes, reference will be made to "Monitor", recognising that upon implementation of the recommendation of merger with the CQC, these functions would be exercised by the merged body. Full recommendations in relation to Monitor appear in the table of recommendations in *Chapter 2* of this executive summary and *Chapter 27* of the main report.

1.139 No NHS trust should be supported to make an application for FT status unless the organisation meets the criteria for authorisation at the date that the application is made. Those criteria must include compliance with the fundamental standards, and any application must be preceded by a physical inspection of its primary clinical areas as well as wards by the CQC. Such criteria must also include compliance with good governance, so as to satisfy the requirement that the fundamental standards are maintainable on an ongoing and regular basis.

1.140 Ongoing obligations of transparency, openness and honesty should be imposed on applicants for FT status, and such obligations include an obligation to disclose to Monitor any significant information material to the application, whether favourable to it or not. Failure to honour such obligations will be subject to the same criminal sanctions outlined below.

1.141 The DH, the NHS Trust Development Authority and Monitor should jointly review the consultation process required to ensure that local opinion has been captured, and this material should be provided to the Secretary of State when assessing any application. The Secretary of State should not support an application unless he or she is satisfied that the applicant is compliant at the time of his decision with fundamental standards and that the commissioner is satisfied that enhanced standards are being complied with, and will continue to be complied with.

1.142 The focus of the process of authorisation must be on fitness for purpose in delivering the appropriate quality of care, and it must include reviews of the standard of service delivered and the ability of the organisation to deliver fundamental standards sustainably. The process of authorisation should include a full physical inspection of the primary clinical areas and wards to determine whether the applicant is compliant.

1.143 Applicants for FT status should be under a duty of utmost good faith to disclose any significant information material to the application.

Accountability of board level directors

1.144 There has been understandable concern at the circumstances surrounding the departure from the Trust of the Chair and Chief Executive. While the business demands of the Trust may have required their swift departure and therefore a commercially understandable compromise, the public demand for accountability was left unsatisfied. Directors should be liable to

disqualification from the role unless they are fit and proper persons for it. The test of fitness should include a requirement to comply with a prescribed code of conduct. A finding that a person is not a fit and proper person should disqualify a person from being a director of any healthcare organisation. Where a regulator is no longer satisfied that a director is a fit and proper person, there should be a power to remove or suspend that person from office after due process. Where a director's employment or appointment is terminated in circumstances where there is reasonable cause to suspect he or she is not a fit and proper person, the organisation should be obliged to report that information to the regulator.

Enhancement of governors' role

1.145 The role of FT governors needs to be enhanced, improved and made accountable.

1.146 Monitor and, post-merger, the CQC, should publish guidance to assist the recognition of the importance and accountability of the public role of a governor, and what is required to be a fit and proper person to undertake such a role and the steps that an FT should take in the event of it needing to disqualify a governor as not fulfilling such criteria.

1.147 Governors should be provided with appropriate training, and consideration should be given to establishing a minimum level of relevant experience, as a requisite to holding a post as a governor.

1.148 Published guidance should also set out the principles that governors should follow to ensure effective public accountability. This should include access to external assistance and support to be provided by their national association.

Supportive agencies

1.149 The NHS Litigation Authority (NHSLA), through its risk management ratings, has made a contribution to the assessment of providers governance, but the significance of this has been misunderstood and sometimes misapplied. The NHSLA should set more demanding levels for financial incentivisation, and arrangements should be made for the more effective sharing and recording of information.

1.150 The functions of the former NPSA with regard to incident reporting and analysis need to be well protected and defined. More could be made of this important source of information.

1.151 The HPA obtained information of potential concern about the Trust's attitude to hospital acquired infections. Its valuable resource of information should be coordinated in conjunction with the NHS Information Centre (NHSIC). Infection control officials should share their concerns with commissioners and regulators wherever there is cause for concern about patient safety.

Effective complaints and incidents

1.152 Complaints, their source, their handling and their outcome provide an insight into the effectiveness of an organisation's ability to uphold both the fundamental standards and the culture of caring. They are a source of information that has hitherto been undervalued as a source of accountability and a basis for improvement.

1.153 The recommendations and standards suggested in the Patients Association's peer review into complaints at the Trust should be reviewed and implemented nationally. They are set out in the full set of recommendations that follow this summary of findings.

1.154 Whilst a uniform process of complaints handling should be applied, the making of a complaint should be easy to do, and any expression of concern made by a patient should be treated as a complaint, unless the patient's permission is refused. The clarity of the responsibility of a senior clinician and nurse for each patient, and their obligation to be involved in responding to any complaint, should facilitate access to the complaints system and facilitate a speedy resolution, wherever possible.

1.155 Whilst a complaints system should be consistent, it must never be applied in a formulaic or insensitive manner.

1.156 Complaints relating to possible breaches of fundamental standards and serious complaints should be accessible to the CQC, relevant commissioners, health scrutiny committees, communities and Local Healthwatch.

1.157 Learning from complaints must be effectively identified, disseminated and implemented, and it must be made known to the complainant and the public, subject to suitable anonymisation.

Commissioning for quality and for improvement: enhanced quality standards

1.158 Owing to a combination of organisational change and implementation of a policy intending to pass them responsibility for quality before the necessary tools for exercising this were available, PCTs were not as effective as might have been expected in commissioning or monitoring delivery of quality.

1.159 Commissioners of services, as the paying party for services they contract from providers, must ensure that those services are well provided and are provided safely. The fundamental standards to be policed by the CQC form the minimum level of service that should be provided, but the commissioner in its contracting arrangements will wish to set standards over and above that minimum standard for the services that it wishes to contract, and will set out redress for non-compliance with those contracted standards.

1.160 These contractual standards – enhanced quality standards – give commissioners the opportunity to promote improvement in the areas of service they wish to purchase. Commissioners could also set out longer term goals for, or in conjunction with, providers by way of developmental standards and focus on improvements in effectiveness.

1.161 The NHS Commissioning Board should be responsible for devising and designing the enhanced standards to be incorporated into commissioning contracts or assisting local commissioners to do so.

1.162 The NHS Commissioning Board and the local commissioners of services must be adequately resourced to enable a proper scrutiny that providers are delivering the standard of service required under their contracts. The resource available to the commissioners to monitor the provision of contractual services should extend as necessary to the capacity to undertake audits, inspections and investigations, of individual cases (bearing in mind that they will have access to individual complaints as outlined above) and of groups of cases. The commissioners must have access to quality accounts and all QRPs available to the CQC.

1.163 Responsibility for driving improvement in the quality of service should therefore rest with the commissioners through their commissioning arrangements. Commissioners should promote improvement by requiring compliance with enhanced standards that demand more of the provider than the fundamental standards.

1.164 Commissioners should have powers of intervention where services are being provided which do not accord with their contracts. If fundamental standards are not being provided, the CQC, as regulator, should also be informed, and the commissioner and the CQC should in such cases be able to act jointly or alone. The commissioner should be able to stop the provision of a service being supplied in breach of the fundamental and/or enhanced standards and/or require the provision of the service to be done in a different way, or by different personnel, to protect patients. The CQC and commissioners should have contingency plans in place in the event of needing to exercise these powers.

1.165 In contracting providers, commissioners – not the provider – should decide what needs to be provided, but they should consider the views of clinicians, including those from providers and elsewhere, on commissioning needs as they consider it appropriate. Commissioners should also consult others, as they deem necessary, including GPs and procurement expertise, to improve their commissioning arrangements. Commissioners should also consult and liaise with other commissioning bodies, as they deem necessary, to achieve the necessary expertise or commissioning power to secure effective arrangements.

1.166 Commissioners should, in their contracts, require the boards of providers to seek and record the views and advice of its clinical and nursing directors of the impact on the fundamental

standards of any proposed major change to clinical or nurse staffing arrangements or the provision of facilities.

1.167 Commissioners need to recognise their accountability to the public they serve by measures designed to involve the public in commissioning and enable their views to be taken into account. For this purpose, commissioners need to raise their public profile.

Local public and patient engagement and partnership

1.168 The arrangements for public and patient involvement, and for local government scrutiny in Stafford, were a conspicuous failure.

1.169 Local authorities should be required to pass over the funds received for the purposes of Local Healthwatch to that organisation which shall become accountable for its use of the funding. Should the Local Healthwatch become incapable of performing its functions, then the local authority or Healthwatch England should intervene, as appropriate.

1.170 Local Healthwatch should work to a consistent structure nationally, with the benefit of appropriate training and access to advice.

1.171 Oversight and scrutiny committees should have power to inspect providers, using information from local patient involvement to trigger such inspections as necessary.

Medical training and education

1.172 Medical education and training systems provide an opportunity for enhancing patient safety. Students and trainees should not be placed in establishments which do not comply with the fundamental standards, and those charged with overseeing and regulating these activities should, like all other participants in the system, make the protection of patients their priority. A number of recommendations for this purpose have been made.

There must be real involvement of patients and the public in all that is done

1.173 The CQC needs to evidence its own compliance with the principles of openness, honesty, transparency and candour described above. It should consider integrating patients through their user group representatives into its structure and/or through liaison with the patient's consultative council. Consideration should also be given to inviting nominated members from groups such as the Academy of Medical Royal Colleges and Nursing and Allied Healthcare Professionals.

1.174 Those with responsibility for commissioning should also seek the involvement of the public, as set out in the full table of recommendations.

1.175 Providers need to review unnecessary restrictions on visiting hours. They should be as open to visitors as would be a patient's home, subject to health protection requirements.

Openness, transparency and candour

1.176 For a common culture to be shared throughout the system, these three characteristics are required:

- Openness: enabling concerns to be raised and disclosed freely without fear, and for questions to be answered;
- Transparency: allowing true information about performance and outcomes to be shared with staff, patients and the public;
- Candour: ensuring that patients harmed by a healthcare service are informed of the fact and that an appropriate remedy is offered, whether or not a complaint has been made or a question asked about it.

1.177 This requires all organisations and those working in them to be honest, open and truthful in all their dealings with patients and the public.

1.178 In addition, organisations and their leaders must be completely truthful when making statements to regulators, and they must not be misleading by omission. Public statements must also be truthful and not misleading.

1.179 The NHS Constitution should include clear obligations to comply with these principles, and all contracts and policies should be reviewed to ensure consistency with them. For example, "gagging" or non-disparagement clauses should not be permitted to limit legitimate disclosure of public interest issues concerning patient safety and care.

1.180 The common culture of caring requires a displacement of a culture of fear with a culture of openness, honesty and transparency, where the only fear is the failure to uphold the fundamental standards and the caring culture.

1.181 A statutory obligation should be imposed:

- On healthcare providers, registered medical and nursing practitioners to observe the duty of candour;
- On directors of healthcare organisations to be truthful in any information given to a regulator or commissioner. There should be a criminal offence for any registered doctor or nurse or allied health professional or director of a registered or authorised organisation to

obstruct the performance of these duties or dishonestly or recklessly to make an untruthful statement to a regulator.

1.182 Enforcement of these duties should rest with the CQC, which should be supported by commissioners' and others' monitoring.

1.183 The CQC should keep on constant review its ability to deliver the necessary regulatory oversight and enforcement, bearing in mind its duties of openness, honesty and candour, and ensure that its strategy and performance are communicated effectively to its staff.

Peer review

1.184 The creation of a caring culture would be greatly assisted if all those involved in the provision of healthcare are prepared to learn lessons from others and to offer up their own practices for peer review. Whilst peer review will have a specific relevance in cases of practitioners where there may be concerns about substandard performance, it has a far more fundamental role in changing behaviour to ensure a consistent and caring culture throughout the healthcare services. Peer review therefore needs to be a key part of the delivery and monitoring of any service or activity, and those involved need to demonstrate that this element of monitoring and learning is integral to the process of compliance with fundamental standards and of improvement.

Caring, compassionate and considerate nursing

1.185 There should be an increased focus on a culture of compassion and caring in nurse recruitment, training and education. Nursing training should ensure that a consistent standard is achieved by all trainees throughout the country. The achievement of this will require the establishment of national standards. The knowledge and skills framework should be reviewed with a view to giving explicit recognition to nurses' commitment to patient care and the priority that should be accorded to dignity and respect in the acquisition of leadership skills.

1.186 Practical hands-on training and experience should be a prerequisite to entry into the nursing profession.

1.187 Training and continuing professional development for nurses should apply at all levels, from student to director, and commissioning arrangements should reflect the need for healthcare services to be delivered by those who are suitably trained.

1.188 Nurse leadership should be enhanced by ensuring that ward nurse managers work in a supervisory capacity and are not office bound. They should be involved and aware of the plans and care for their patients.

1.189 The NMC should introduce a system of revalidation similar to that of the GMC as a means of reinforcing the status and competence of registered nurses as well as providing additional protection to the public. It is essential that the NMC has the resources and the administrative and leadership skills to ensure that this does not detract from its existing core function of regulating fitness to practise.

1.190 There should be a responsible officer for nursing in each trust, and they should be accountable to the NMC.

1.191 Consideration should be given by the NMC to introducing an aptitude test to be taken by aspirant registered nurses prior to entering into the profession to explore the candidate's attitude towards caring, compassion and other necessary professional values. Once nurses have received appropriate training, the NMC should ensure the professional development of registrants and should ensure that nurses' training is more practical.

1.192 The special requirements of caring for the elderly should be recognised by consideration of the introduction of a new status of a registered older person's nurse.

1.193 The professional voice needs to be strengthened:

- The RCN should consider how better to separate its trade union and professional representative functions.
- A forum of nursing directors should be formed.
- There should be at least one nurse on the executive boards of all healthcare organisations, including commissioners.
- The advice of the nursing director should be obtained and recorded in relation to the impact on the quality of care and patient safety of any proposed major change in nurse staffing or facilities.

Healthcare support workers

1.194 Currently, healthcare support workers, whether working for the NHS or for independent healthcare providers, in the community or for agencies, are not subject to any system of registration. A registration system should be created under which no unregistered person should be permitted to provide for reward direct physical care to patients currently under the care and treatment of a registered nurse or a registered doctor or who are dependent on such care by reason of disability or infirmity in any hospital or care home setting. Exemptions will need to be made for persons caring for members of their own family or those with whom they have a genuine social relationship.

1.195 There should be a uniform code of conduct that would apply to all healthcare support workers who should receive education and training in accordance with common national standards. The necessary code of conduct, education and training standards should be prepared and maintained by the NMC after due consultation with all relevant stakeholders. There should be a means whereby members of the public can clearly identify and distinguish between registered nurses and registered healthcare workers.

Leadership

1.196 The common culture and values of the NHS must be applied at all levels of the organisation, but of particular importance is the example set by leaders. A leadership staff college should be created to provide common professional training in management and leadership to potential senior staff. This could lead to an accreditation scheme enhancing eligibility for consideration for such roles and will have the effect of promoting and researching best practice.

1.197 This college should not be a "virtual organisation" facilitating events. It should be a physical presence that will serve the role of reinforcing the required culture through shared experience and will provide a common induction into the expectations of the NHS of those who lead and work in the system.

1.198 A common code of ethics, standards and conduct for senior board-level healthcare leaders and managers should be produced and should be consistent with the common culture. The principles appearing in those ethics and standards should apply to all staff, and it is the responsibility of employers to ensure that they are honoured. Serious non-compliance with the code should be grounds for considering a leader not a fit and proper person to be a director. An alternative would be to set up a professional regulator, the need for which could be better assessed after reviewing experience with the "fit and proper person" requirements.

1.199 Accreditation schemes for managers promoted by the staff college should be considered.

1.200 Appraisal systems are a key tool to monitor and enforce standards and to reinforce a caring culture. The GMC and the NMC should introduce common minimum standards for appraisal and support with which registered members would be obliged to comply.

1.201 As a part of this mandatory annual performance appraisal, each clinician and nurse should be required to demonstrate their ongoing commitment, compassion and caring shown towards patients, evidenced by feedback of the appraisee from patients and families, as well as from colleagues and co-workers. This portfolio could be made available to the GMC or the NMC, if requested as part of the revalidation process.

Proactive professional regulation of fitness to practise

1.202 Both the GMC and the NMC should have a clear policy stating the circumstances in which they should be informed of generic complaints. Both should aim to be more proactive in monitoring fitness to practise, launching their own proactive investigations where appropriate.

1.203 The GMC should also give guidance to deaneries (or their successors) of the nature of matters to be reported, which should not be limited to exceptional matters of perceived non-compliance with standards.

1.204 The GMC and the NMC should ensure that patients' safety is the first priority of medical training and education.

1.205 To be more effective, it is more likely that there will be a need for increased resource. Both the GMC and the NMC should, as appropriate, liaise more closely with the CQC, and the three organisations should report regularly on their work. Other reviews suggest that the NMC is still to be found wanting in the administration of its functions; this needs to be remedied lest the regulatory gap widen, rather than narrow and close.

1.206 The GMC and the NMC should consider commissioning peer reviews, possibly in conjunction with the CQC, if generic concerns exist which might lead to individual concerns.

1.207 The GMC should systematise the exchange of information between it and the Royal Colleges.

1.208 Fitness to practise procedures should not delay or obstruct internal disciplinary actions taken by providers, so far as is practicable. Employment disciplinary procedures should be reviewed accordingly.

1.209 The same event, or series of events, may lead to fitness to practise procedures arising in more than one professional regulator. The Professional Standards Authority for Health and Social Care (PSA), formerly CHRE, should consider devising procedures to allow a common independent tribunal to determine fitness to practise issues and sanctions across the healthcare professional field.

1.210 Further recommendations to improve the profile and performance of the regulators are included in the table that follows this summary of findings.

Caring for patients: approaches applicable to all but in particular the elderly

1.211 Hospitals should review, with a view to reinstatement, the practice of identifying a consultant or senior clinician and nurse who is in charge of each patient's care, so that patients and families are clear who is in overall charge of that care. Those persons in charge and

responsible for a patient's care should be directly responsible for assisting in the response to any complaints that may be lodged in relation to the quality of care that that patient has received.

1.212 Ward sisters and nurse managers should operate in a supervisory capacity and should not be office bound. The ward manager should know about the care plans relating to every patient on their ward and should be visible and accessible to patients and staff alike. Ward managers should work alongside staff as a role model and mentor, developing clinical competencies and leadership skills within the team and ensuring that the caring culture expected of professional staff is being consistently maintained and upheld.

1.213 No ward round should take place without the presence of the nurse in charge of the patients that are to be visited (or an appointed deputy or other replacement).

1.214 Regular interaction and engagement between nurses and patients should be systemised through regular ward rounds.

1.215 A truly caring culture does not stop at the door of the hospital provider. It should never be acceptable for patients to be discharged at any time without knowledge that the patient in need of care will receive it on arrival at their destination. The emphasis should be on continuity of care to include a follow-up as to a patient's well-being after discharge.

1.216 Continuity of care should also apply to the administration of medication, which should be overseen by the nurse in charge of the ward, and all necessary checks should be undertaken, particularly in the event of patient movement in or out of the ward.

1.217 This ongoing responsibility for continuing care should also embrace GPs and their practices. GPs should, as a part of their professional obligations, check on their patient after hospital treatment and assess whether the outcomes were satisfactory. GP practices should also monitor patterns of concern which should be made known to the CQC and the relevant commissioner.

1.218 GPs should have an obligation to their patients to keep themselves informed of the standard of service available from providers.

Information

1.219 If the culture of those engaged in and with the NHS is to change, information must be made available about the performance and outcomes of the service provided to enable patients to make treatment choices and have a proper understanding of the outcomes for them.

1.220 The public should be able to compare relative performance, and therefore need access to open, honest and transparent information to assess compliance with appropriate standards. To achieve the culture that is necessary for the NHS to flourish, every healthcare organisation and everybody working within the healthcare system must be honest, open and truthful in all their dealings with patients and the public. No personal or organisational interest must ever be allowed to outweigh the duty to be honest, open and truthful.

1.221 Transparency and patient safety would be greatly enhanced by the introduction of user friendly electronic patient record systems. Patients should be able to in real time, or retrospectively, read and comment on their records. The system should be designed to include prompts and defaults to contribute to effective patient care and safety.

1.222 All healthcare provider organisations should develop and publish real time information on the performance of their consultants and specialist teams in relation to mortality, morbidity, outcome and patient satisfaction, and on the performance of each team and their services against the fundamental standards.

1.223 It must be a professional duty of healthcare professionals to collaborate in the provision of such information.

1.224 This information, available in as near real time as possible to providers, commissioners, regulators and the public, should include not only statistics of outcomes, but also all other available safety-related information, including that derived from investigations, complaints and incidents.

1.225 Every provider organisation should have a designated board member as a chief information officer.

Quality accounts

1.226 Trust Boards should provide, through quality accounts, full and accurate information about their compliance or non-compliance with the fundamental standards and enhanced standards that apply to them. This data should be made available on each trust's website, and should be audited.

1.227 Quality accounts should contain information in a common form to enable comparisons to be made between organisations. This should include a minimum of prescribed information about compliance with fundamental and enhanced standards. Where there are issues of non-compliance, proposals for rectification should appear, and full details should be given on statistics on mortality and other outcomes. These quality accounts should contain the observations of commissioners and overview and scrutiny committees.

1.228 Each quality account should be accompanied by a declaration signed by all directors certifying the accounts to be true, or a statement of explanation should be given as to why any director is unable to sign or has refused to sign such a declaration. To make or be party to a wilfully or recklessly false statement as to compliance with fundamental standards in the required quality account should be made a criminal offence.

1.229 Healthcare providers should have their quality accounts independently audited and their accuracy, fairness, and balance should be considered by the CQC, exercising its regulatory jurisdiction.

Health and Social Care Information Centre

1.230 The Health and Social Care Information Centre should be set up as an organisation tasked with the independent collection, analysis, publication and oversight of healthcare information. This body should house the information functions previously held by the NPSA.

1.231 This body should publish detailed breakdowns of clinically related complaints, SUIs, and other quality-related information.

Maintenance of an effective health service requires stability

1.232 Before a proposal for any major structural change to the healthcare system is accepted, an impact and risk assessment should be undertaken by the DH and should be debated publicly. The merging of functions between Monitor and the CQC should be planned and timed carefully.

1.233 The NHS Commissioning Board should develop and oversee a code of practice to ensure that any future transitions are planned and managed accordingly, to deliverable timescales, in a candid and comprehensive manner. Corporate memory and information and documentation should be maintained. This code should include transitions between commissioners (eg as new clinical commissioning groups are formed) and guidance to commissioners on managing providers' transitions.

The Department of Health leadership

1.234 The DH should ensure senior clinical involvement in all decisions which may impact upon patients' safety and well-being.

1.235 DH officials need to connect more to the NHS and its patients, and they need personal contact with those who have suffered poor experiences. Consideration should be given to involving a patient/service user representative service as a consultative forum within the DH.

Conclusion

1.236 The first inquiry report stated that it should be patients – not numbers – which counted. That remains the view of this Inquiry. The demands for financial control, corporate governance, commissioning and regulatory systems are understandable and in many cases necessary, but it is not the system itself which will ensure that the patient is put first day in and day out. It is the people working in the health service and those charged with developing healthcare policy that need to ensure that is the case.

1.237 The extent of the failure of the system shown in this Inquiry's report suggests that a fundamental culture change is needed. That does not require a root and branch reorganisation – the system has had many of those – but it requires changes which can largely be implemented within the system that has now been created by the new reforms. I hope that the recommendations in this report can contribute to that end and put patients where they are entitled to be – the first and foremost consideration of the system and everyone who works in it.

2. Table of recommendations

Rec. no.	Theme	Recommendation	Chapter
	Accountability for implementation of the recommendations These recommendations require every single person serving patients to contribute to a safer, committed and compassionate and caring service.		
1	Implementing the recommendations	It is recommended that: • All commissioning, service provision regulatory and ancillary organisations in healthcare should consider the findings and recommendations of this report and decide how to apply them to their own work; • Each such organisation should announce at the earliest practicable time its decision on the extent to which it accepts the recommendations and what it intends to do to implement those accepted, and thereafter, on a regular basis but not less than once a year, publish in a report information regarding its progress in relation to its planned actions; • In addition to taking such steps for itself, the Department of Health should collate information about the decisions and actions generally and publish on a regular basis but not less than once a year the progress reported by other organisations; • The House of Commons Select Committee on Health should be invited to consider incorporating into its reviews of the performance of organisations accountable to Parliament a review of the decisions and actions they have taken with regard to the recommendations in this report.	Introduction
2		The NHS and all who work for it must adopt and demonstrate a shared culture in which the patient is the priority in everything done. This requires: • A common set of core values and standards shared throughout the system; • Leadership at all levels from ward to the top of the Department of Health, committed to and capable of involving all staff with those values and standards; • A system which recognises and applies the values of transparency, honesty and candour; • Freely available, useful, reliable and full information on attainment of the values and standards; • A tool or methodology such as a cultural barometer to measure the cultural health of all parts of the system.	20
	Putting the patient first The patients must be the first priority in all of what the NHS does. Within available resources, they must receive effective services from caring, compassionate and committed staff, working within a common culture, and they must be protected from avoidable harm and any deprivation of their basic rights.		
3	Clarity of values and principles	The NHS Constitution should be the first reference point for all NHS patients and staff and should set out the system's common values, as well as the respective rights, legitimate expectations and obligations of patients.	21
4		The core values expressed in the NHS Constitution should be given priority of place and the overriding value should be that patients are put first, and everything done by the NHS and everyone associated with it should be informed by this ethos.	21

Rec. no.	Theme	Recommendation	Chapter
5		In reaching out to patients, consideration should be given to including expectations in the NHS Constitution that: • Staff put patients before themselves; • They will do everything in their power to protect patients from avoidable harm; • They will be honest and open with patients regardless of the consequences for themselves; • Where they are unable to provide the assistance a patient needs, they will direct them where possible to those who can do so; • They will apply the NHS values in all their work.	21
6		The handbook to the NHS Constitution should be revised to include a much more prominent reference to the NHS values and their significance.	21
7		All NHS staff should be required to enter into an express commitment to abide by the NHS values and the Constitution, both of which should be incorporated into the contracts of employment.	21
8		Contractors providing outsourced services should also be required to abide by these requirements and to ensure that staff employed by them for these purposes do so as well. These requirements could be included in the terms on which providers are commissioned to provide services.	21
	Fundamental standards of behaviour Enshrined in the NHS Constitution should be the commitment to fundamental standards which need to be applied by all those who work and serve in the healthcare system. Behaviour at all levels needs to be in accordance with at least these fundamental standards.		
9		The NHS Constitution should include reference to all the relevant professional and managerial codes by which NHS staff are bound, including the Code of Conduct for NHS Managers.	21
10		The NHS Constitution should incorporate an expectation that staff will follow guidance and comply with standards relevant to their work, such as those produced by the National Institute for Health and Clinical Excellence and, where relevant, the Care Quality Commission, subject to any more specific requirements of their employers.	21
11		Healthcare professionals should be prepared to contribute to the development of, and comply with, standard procedures in the areas in which they work. Their managers need to ensure that their employees comply with these requirements. Staff members affected by professional disagreements about procedures must be required to take the necessary corrective action, working with their medical or nursing director or line manager within the trust, with external support where necessary. Professional bodies should work on devising evidence-based standard procedures for as many interventions and pathways as possible.	20
12		Reporting of incidents of concern relevant to patient safety, compliance with fundamental standards or some higher requirement of the employer needs to be not only encouraged but insisted upon. Staff are entitled to receive feedback in relation to any report they make, including information about any action taken or reasons for not acting.	2

Rec. no.	Theme	Recommendation	Chapter
	A common culture made real throughout the system – an integrated hierarchy of standards of service No provider should provide, and there must be zero tolerance of, any service that does not comply with fundamental standards of service. Standards need to be formulated to promote the likelihood of the service being delivered safely and effectively, to be clear about what has to be done to comply, to be informed by an evidence base and to be effectively measurable.		
13	The nature of standards	Standards should be divided into: • Fundamental standards of minimum safety and quality – in respect of which non-compliance should not be tolerated. Failures leading to death or serious harm should remain offences for which prosecutions can be brought against organisations. There should be a defined set of duties to maintain and operate an effective system to ensure compliance; • Enhanced quality standards – such standards could set requirements higher than the fundamental standards but be discretionary matters for commissioning and subject to availability of resources; • Developmental standards which set out longer term goals for providers – these would focus on improvements in effectiveness and are more likely to be the focus of commissioners and progressive provider leadership than the regulator. All such standards would require regular review and modification.	21
14		In addition to the fundamental standards of service, the regulations should include generic requirements for a governance system designed to ensure compliance with fundamental standards, and the provision and publication of accurate information about compliance with the fundamental and enhanced standards.	9
15		All the required elements of governance should be brought together into one comprehensive standard. This should require not only evidence of a working system but also a demonstration that it is being used to good effect.	11
16	Responsibility for setting standards	The Government, through regulation, but after so far as possible achieving consensus between the public and professional representatives, should provide for the fundamental standards which should define outcomes for patients that must be avoided. These should be limited to those matters that it is universally accepted should be avoided for individual patients who are accepted for treatment by a healthcare provider.	21
17		The NHS Commissioning Board together with Clinical Commissioning Groups should devise enhanced quality standards designed to drive improvement in the health service. Failure to comply with such standards should be a matter for performance management by commissioners rather than the regulator, although the latter should be charged with enforcing the provision by providers of accurate information about compliance to the public.	21
18		It is essential that professional bodies in which doctors and nurses have confidence are fully involved in the formulation of standards and in the means of measuring compliance.	21
	Responsibility for, and effectiveness of, healthcare standards		
19	Gaps between the understood functions of separate regulators	There should be a single regulator dealing both with corporate governance, financial competence, viability and compliance with patient safety and quality standards for all trusts.	10

Rec. no.	Theme	Recommendation	Chapter
20	Responsibility for regulating and monitoring compliance	The Care Quality Commission should be responsible for policing the fundamental standards, through the development of its core outcomes, by specifying the indicators by which it intends to monitor compliance with those standards. It should be responsible not for directly policing compliance with any enhanced standards but for regulating the accuracy of information about compliance with them.	21
21		The regulator should have a duty to monitor the accuracy of information disseminated by providers and commissioners on compliance with standards and their compliance with the requirement of honest disclosure. The regulator must be willing to consider individual cases of gross failure as well as systemic causes for concern.	21
22		The National Institute for Health and Clinical Excellence should be commissioned to formulate standard procedures and practice designed to provide the practical means of compliance, and indicators by which compliance with both fundamental and enhanced standards can be measured. These measures should include both outcome and process based measures, and should as far as possible build on information already available within the system or on readily observable behaviour.	21
23		The measures formulated by the National Institute for Health and Clinical Excellence should include measures not only of clinical outcomes, but of the suitability and competence of staff, and the culture of organisations. The standard procedures and practice should include evidence-based tools for establishing what each service is likely to require as a minimum in terms of staff numbers and skill mix. This should include nursing staff on wards, as well as clinical staff. These tools should be created after appropriate input from specialties, professional organisations, and patient and public representatives, and consideration of the benefits and value for money of possible staff: patient ratios.	21
24		Compliance with regulatory fundamental standards must be capable so far as possible of being assessed by measures which are understood and accepted by the public and healthcare professionals.	21
25		It should be considered the duty of all specialty professional bodies, ideally together with the National Institute for Health and Clinical Excellence, to develop measures of outcome in relation to their work and to assist in the development of measures of standards compliance.	21
26		In policing compliance with standards, direct observation of practice, direct interaction with patients, carers and staff, and audit of records should take priority over monitoring and audit of policies and protocols. The regulatory system should retain the capacity to undertake in-depth investigations where these appear to be required.	9
27		The healthcare systems regulator should promote effective enforcement by: use of a low threshold of suspicion; no tolerance of non-compliance with fundamental standards; and allowing no place for favourable assumptions, unless there is evidence showing that suspicions are ill-founded or that deficiencies have been remedied. It requires a focus on identifying what is wrong, not on praising what is right.	9
28	Sanctions and interventions for non-compliance	Zero tolerance: A service incapable of meeting fundamental standards should not be permitted to continue. Breach should result in regulatory consequences attributable to an organisation in the case of a system failure and to individual accountability where individual professionals are responsible. Where serious harm or death has resulted to a patient as a result of a breach of the fundamental standards, criminal liability should follow and failure to disclose breaches of these standards to the affected patient (or concerned relative) and a regulator should also attract regulatory consequences. Breaches not resulting in actual harm but which have exposed patients to a continuing risk of harm to which they would not otherwise have been exposed should also be regarded as unacceptable.	21

Rec. no.	Theme	Recommendation	Chapter
29		It should be an offence for death or serious injury to be caused to a patient by a breach of these regulatory requirements, or, in any other case of breach, where a warning notice in respect of the breach has been served and the notice has not been complied with. It should be a defence for the provider to prove that all reasonably practicable steps have been taken to prevent a breach, including having in place a prescribed system to prevent such a breach.	21
30	Interim measures	The healthcare regulator must be free to require or recommend immediate protective steps where there is reasonable cause to suspect a breach of fundamental standards, even if it has yet to reach a concluded view or acquire all the evidence. The test should be whether it has reasonable grounds in the public interest to make the interim requirement or recommendation.	9
31		Where aware of concerns that patient safety is at risk, Monitor and all other regulators of healthcare providers must have in place policies which ensure that they constantly review whether the need to protect patients requires use of their own powers of intervention to inform a decision whether or not to intervene, taking account of, but not being bound by, the views or actions of other regulators.	10
32		Where patient safety is believed on reasonable grounds to be at risk, Monitor and any other regulator should be obliged to take whatever action within their powers is necessary to protect patient safety. Such action should include, where necessary, temporary measures to ensure such protection while any investigation required to make a final determination is undertaken.	10
33		Insofar as healthcare regulators consider they do not possess any necessary interim powers, the Department of Health should consider introduction of the necessary amendments to legislation to provide such powers.	10
34		Where a provider is under regulatory investigation, there should be some form of external performance management involvement to oversee any necessary interim arrangements for protecting the public.	9
35	Need to share information between regulators	Sharing of intelligence between regulators needs to go further than sharing of existing concerns identified as risks. It should extend to all intelligence which when pieced together with that possessed by partner organisations may raise the level of concern. Work should be done on a template of the sort of information each organisation would find helpful.	9
36	Use of information for effective regulation	A coordinated collection of accurate information about the performance of organisations must be available to providers, commissioners, regulators and the public, in as near real time as possible, and should be capable of use by regulators in assessing the risk of non-compliance. It must not only include statistics about outcomes, but must take advantage of all safety related information, including that capable of being derived from incidents, complaints and investigations.	9
37	Use of information about compliance by regulator from: • Quality accounts	Trust Boards should provide, through quality accounts, and in a nationally consistent format, full and accurate information about their compliance with each standard which applies to them. To the extent that it is not practical in a written report to set out detail, this should be made available via each trust's website. Reports should no longer be confined to reports on achievements as opposed to a fair representation of areas where compliance has not been achieved. A full account should be given as to the methods used to produce the information. To make or be party to a wilfully or recklessly false statement as to compliance with safety or essential standards in the required quality account should be made a criminal offence.	11

Rec. no.	Theme	Recommendation	Chapter
38	• Complaints	The Care Quality Commission should ensure as a matter of urgency that it has reliable access to all useful complaints information relevant to assessment of compliance with fundamental standards, and should actively seek this information out, probably via its local relationship managers. Any bureaucratic or legal obstacles to this should be removed.	11
39		The Care Quality Commission should introduce a mandated return from providers about patterns of complaints, how they were dealt with and outcomes.	11
40		It is important that greater attention is paid to the narrative contained in, for instance, complaints data, as well as to the numbers.	11
41	• Patient safety alerts	The Care Quality Commission should have a clear responsibility to review decisions not to comply with patient safety alerts and to oversee the effectiveness of any action required to implement them. Information-sharing with the Care Quality Commission regarding patient safety alerts should continue following the transfer of the National Patient Safety Agency's functions in June 2012 to the NHS Commissioning Board.	11
42	• Serious untoward incidents	Strategic Health Authorities/their successors should, as a matter of routine, share information on serious untoward incidents with the Care Quality Commission.	11
43	• Media	Those charged with oversight and regulatory roles in healthcare should monitor media reports about the organisations for which they have responsibility.	6
44		Any example of a serious incident or avoidable harm should trigger an examination by the Care Quality Commission of how that was addressed by the provider and a requirement for the trust concerned to demonstrate that the learning to be derived has been successfully implemented.	11
45	• Inquests	The Care Quality Commission should be notified directly of upcoming healthcare-related inquests, either by trusts or perhaps more usefully by coroners.	11
46	• Quality and risk profiles	The Quality and Risk Profile should not be regarded as a potential substitute for active regulatory oversight by inspectors. It is important that this is explained carefully and clearly as and when the public are given access to the information.	11
47	• Foundation trust governors, scrutiny committees	The Care Quality Commission should expand its work with overview and scrutiny committees and foundation trust governors as a valuable information resource. For example, it should further develop its current 'sounding board events'.	11
48		The Care Quality Commission should send a personal letter, via each registered body, to each foundation trust governor on appointment, inviting them to submit relevant information about any concerns to the Care Quality Commission.	11
49	Enhancement of monitoring and the importance of inspection	Routine and risk-related monitoring, as opposed to acceptance of self-declarations of compliance, is essential. The Care Quality Commission should consider its monitoring in relation to the value to be obtained from: • The Quality and Risk Profile; • Quality Accounts; • Reports from Local Healthwatch; • New or existing peer review schemes; • Themed inspections.	11
50		The Care Quality Commission should retain an emphasis on inspection as a central method of monitoring non-compliance.	11

Rec. no.	Theme	Recommendation	Chapter
51		The Care Quality Commission should develop a specialist cadre of inspectors by thorough training in the principles of hospital care. Inspections of NHS hospital care providers should be led by such inspectors who should have the support of a team, including service user representatives, clinicians and any other specialism necessary because of particular concerns. Consideration should be given to applying the same principle to the independent sector, as well as to the NHS.	11
52		The Care Quality Commission should consider whether inspections could be conducted in collaboration with other agencies, or whether they can take advantage of any peer review arrangements available.	11
53	Care Quality Commission independence, strategy and culture	Any change to the Care Quality Commission's role should be by evolution – any temptation to abolish this organisation and create a new one must be avoided.	11
54		Where issues relating to regulatory action are discussed between the Care Quality Commission and other agencies, these should be properly recorded to avoid any suggestion of inappropriate interference in the Care Quality Commission's statutory role.	11
55		The Care Quality Commission should review its processes as a whole to ensure that it is capable of delivering regulatory oversight and enforcement effectively, in accordance with the principles outlined in this report.	11
56		The leadership of the Care Quality Commission should communicate clearly and persuasively its strategic direction to the public and to its staff, with a degree of clarity that may have been missing to date.	11
57		The Care Quality Commission should undertake a formal evaluation of how it would detect and take action on the warning signs and other events giving cause for concern at the Trust described in this report, and in the report of the first inquiry, and open that evaluation for public scrutiny.	11
58		Patients, through their user group representatives, should be integrated into the structure of the Care Quality Commission. It should consider whether there is a place for a patients' consultative council with which issues could be discussed to obtain a patient perspective directly.	11
59		Consideration should be given to the introduction of a category of nominated board members from representatives of the professions, for example, the Academy of Medical Royal Colleges, a representative of nursing and allied healthcare professionals, and patient representative groups.	11
	Responsibility for, and effectiveness of, regulating healthcare systems governance – Monitor's healthcare systems regulatory functions		
60	Consolidation of regulatory functions	The Secretary of State should consider transferring the functions of regulating governance of healthcare providers and the fitness of persons to be directors, governors or equivalent persons from Monitor to the Care Quality Commission.	11 10
61		A merger of system regulatory functions between Monitor and the Care Quality Commission should be undertaken incrementally and after thorough planning. Such a move should not be used as a justification for reduction of the resources allocated to this area of regulatory activity. It would be vital to retain the corporate memory of both organisations.	11 10
62	Improved patient focus	For as long as it retains responsibility for the regulation of foundation trusts, Monitor should incorporate greater patient and public involvement into its own structures, to ensure this focus is always at the forefront of its work.	11 10
63	Improved transparency	Monitor should publish all side letters and any rating issued to trusts as part of their authorisation or licence.	10

Rec. no.	Theme	Recommendation	Chapter
64	Authorisation of foundation trusts	The authorisation process should be conducted by one regulator, which should be equipped with the relevant powers and expertise to undertake this effectively. With due regard to protecting the public from the adverse consequences inherent to any reorganisation, the regulation of the authorisation process and compliance with foundation trust standards should be transferred to the Care Quality Commission, which should incorporate the relevant departments of Monitor.	4
65	Quality of care as a pre-condition for foundation trust applications	The NHS Trust Development Authority should develop a clear policy requiring proof of fitness for purpose in delivering the appropriate quality of care as a pre-condition to consideration for support for a foundation trust application.	4
66	Improving contribution of stakeholder opinions	The Department of Health, the NHS Trust Development Authority and Monitor should jointly review the stakeholder consultation process with a view to ensuring that: • Local stakeholder and public opinion is sought on the fitness of a potential applicant NHS trust for foundation trust status and in particular on whether a potential applicant is delivering a sustainable service compliant with fundamental standards; • An accessible record of responses received is maintained; • The responses are made available for analysis on behalf of the Secretary of State, and, where an application is assessed by it, Monitor.	4
67	Focus on compliance with fundamental standards	The NHS Trust Development Authority should develop a rigorous process for the assessment as well as the support of potential applicants for foundation trust status. The assessment must include as a priority focus a review of the standard of service delivered to patients, and the sustainability of a service at the required standard.	4
68		No NHS trust should be given support to make an application to Monitor unless, in addition to other criteria, the performance manager (the Strategic Health Authority cluster, the Department of Health team, or the NHS Trust Development Authority) is satisfied that the organisation currently meets Monitor's criteria for authorisation and that it is delivering a sustainable service which is, and will remain, safe for patients, and is compliant with at least fundamental standards.	4
69		The assessment criteria for authorisation should include a requirement that applicants demonstrate their ability to consistently meet fundamental patient safety and quality standards at the same time as complying with the financial and corporate governance requirements of a foundation trust.	4
70	Duty of utmost good faith	A duty of utmost good faith should be imposed on applicants for foundation trust status to disclose to the regulator any significant information material to the application and to ensure that any information is complete and accurate. This duty should continue throughout the application process, and thereafter in relation to the monitoring of compliance.	4
71	Role of Secretary of State	The Secretary of State's support for an application should not be given unless he is satisfied that the proposed applicant provides a service to patients which is, at the time of his consideration, safe, effective and compliant with all relevant standards, and that in his opinion it is reasonable to conclude that the proposed applicant will continue to be able to do so for the foreseeable future. In deciding whether he can be so satisfied, the Secretary of State should have regard to the required public consultation and should consult with the healthcare regulator.	4
72	Assessment process for authorisation	The assessment for an authorisation of applicant for foundation trust status should include a full physical inspection of its primary clinical areas as well as all wards to determine whether it is compliant with fundamental safety and quality standards.	4

Rec. no.	Theme	Recommendation	Chapter
73	Need for constructive working with other parts of the system	The Department of Health's regular performance reviews of Monitor (and the Care Quality Commission) should include an examination of its relationship with the Department of Health and whether the appropriate degree of clarity of understanding of the scope of their respective responsibilities has been maintained.	10
74	Enhancement of role of governors	Monitor and the Care Quality Commission should publish guidance for governors suggesting principles they expect them to follow in recognising their obligation to account to the public, and in particular in arranging for communication with the public served by the foundation trust and to be informed of the public's views about the services offered.	10
75		The Council of Governors and the board of each foundation trust should together consider how best to enhance the ability of the council to assist in maintaining compliance with its obligations and to represent the public interest. They should produce an agreed published description of the role of the governors and how it is planned that they perform it. Monitor and the Care Quality Commission should review these descriptions and promote what they regard as best practice.	10
76		Arrangements must be made to ensure that governors are accountable not just to the immediate membership but to the public at large – it is important that regular and constructive contact between governors and the public is maintained.	10
77		Monitor and the NHS Commissioning Board should review the resources and facilities made available for the training and development of governors to enhance their independence and ability to expose and challenge deficiencies in the quality of the foundation trust's services.	10
78		The Care Quality Commission and Monitor should consider how best to enable governors to have access to a similar advisory facility in relation to compliance with healthcare standards as will be available for compliance issues in relation to breach of a licence (pursuant to section 39A of the National Health Service Act 2006 as amended), or other ready access to external assistance.	10
79	Accountability of providers' directors	There should be a requirement that all directors of all bodies registered by the Care Quality Commission as well as Monitor for foundation trusts are, and remain, fit and proper persons for the role. Such a test should include a requirement to comply with a prescribed code of conduct for directors.	10
80		A finding that a person is not a fit and proper person on the grounds of serious misconduct or incompetence should be a circumstance added to the list of disqualifications in the standard terms of a foundation trust's constitution.	11
81		Consideration should be given to including in the criteria for fitness a minimum level of experience and/or training, while giving appropriate latitude for recognition of equivalence.	11
82		Provision should be made for regulatory intervention to require the removal or suspension from office after due process of a person whom the regulator is satisfied is not or is no longer a fit and proper person, regardless of whether the trust is in significant breach of its authorisation or licence.	10
83		If a "fit and proper person test" is introduced as recommended, Monitor should issue guidance on the principles on which it would exercise its power to require the removal or suspension or disqualification of directors who did not fulfil it, and the procedure it would follow to ensure due process.	10

Rec. no.	Theme	Recommendation	Chapter
84		Where the contract of employment or appointment of an executive or non-executive director is terminated in circumstances in which there are reasonable grounds for believing that he or she is not a fit and proper person to hold such a post, licensed bodies should be obliged by the terms of their licence to report the matter to Monitor, the Care Quality Commission and the NHS Trust Development Authority.	10
85		Monitor and the Care Quality Commission should produce guidance to NHS and foundation trusts on procedures to be followed in the event of an executive or non-executive director being found to have been guilty of serious failure in the performance of his or her office, and in particular with regard to the need to have regard to the public interest in protection of patients and maintenance of confidence in the NHS and the healthcare system.	10
86	Requirement of training of directors	A requirement should be imposed on foundation trusts to have in place an adequate programme for the training and continued development of directors.	10
	Responsibility for, and effectiveness of, regulating healthcare systems governance – Health and Safety Executive functions in healthcare settings		
87	Ensuring the utility of a health and safety function in a clinical setting	The Health and Safety Executive is clearly not the right organisation to be focusing on healthcare. Either the Care Quality Commission should be given power to prosecute 1974 Act offences or a new offence containing comparable provisions should be created under which the Care Quality Commission has power to launch a prosecution.	13
88	Information sharing	The information contained in reports for the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations should be made available to healthcare regulators through the serious untoward incident system in order to provide a check on the consistency of trusts' practice in reporting fatalities and other serious incidents.	13
89		Reports on serious untoward incidents involving death of or serious injury to patients or employees should be shared with the Health and Safety Executive.	13
90	Assistance in deciding on prosecutions	In order to determine whether a case is so serious, either in terms of the breach of safety requirements or the consequences for any victims, that the public interest requires individuals or organisations to be brought to account for their failings, the Health and Safety Executive should obtain expert advice, as is done in the field of healthcare litigation and fitness to practise proceedings.	13
	Enhancement of the role of supportive agencies		
91	**NHS Litigation Authority** Improvement of risk management	The Department of Health and NHS Commissioning Board should consider what steps are necessary to require all NHS providers, whether or not they remain members of the NHS Litigation Authority scheme, to have and to comply with risk management standards at least as rigorous as those required by the NHS Litigation Authority.	15
92		The financial incentives at levels below level 3 should be adjusted to maximise the motivation to reach level 3.	15
93		The NHS Litigation Authority should introduce requirements with regard to observance of the guidance to be produced in relation to staffing levels, and require trusts to have regard to evidence-based guidance and benchmarks where these exist and to demonstrate that effective risk assessments take place when changes to the numbers or skills of staff are under consideration. It should also consider how more outcome based standards could be designed to enhance the prospect of exploring deficiences in risk management, such as occurred at the Trust.	15

Rec. no.	Theme	Recommendation	Chapter
94	Evidence-based assessment	As some form of running record of the evidence reviewed must be retained on each claim in order for these reports to be produced, the NHS Litigation Authority should consider development of a relatively simple database containing the same information.	15
95	Information sharing	As the interests of patient safety should prevail over the narrow litigation interest under which confidentiality or even privilege might be claimed over risk reports, consideration should also be given to allowing the Care Quality Commission access to these reports.	15
96		The NHS Litigation Authority should make more prominent in its publicity an explanation comprehensible to the general public of the limitations of its standards assessments and of the reliance which can be placed on them.	15
97	**National Patient Safety Agency functions**	The National Patient Safety Agency's resources need to be well protected and defined. Consideration should be given to the transfer of this valuable function to a systems regulator.	17
98		Reporting to the National Reporting and Learning System of all significant adverse incidents not amounting to serious untoward incidents but involving harm to patients should be mandatory on the part of trusts.	17
99		The reporting system should be developed to make more information available from this source. Such reports are likely to be more informative than the corporate version where an incident has been properly reported, and invaluable where it has not been.	17
100		Individual reports of serious incidents which have not been otherwise reported should be shared with a regulator for investigation, as the receipt of such a report may be evidence that the mandatory system has not been complied with.	17
101		While it may be impracticable for the National Patient Safety Agency or its successor to have its own team of inspectors, it should be possible to organise for mutual peer review inspections or the inclusion in Patient Environment Action Team representatives from outside the organisation. Consideration could also be given to involvement from time to time of a representative of the Care Quality Commission.	17
102	Transparency, use and sharing of information	Data held by the National Patient Safety Agency or its successor should be open to analysis for a particular purpose, or others facilitated in that task.	17
103		The National Patient Safety Agency or its successor should regularly share information with Monitor.	17
104		The Care Quality Commission should be enabled to exploit the potential of the safety information obtained by the National Patient Safety Agency or its successor to assist it in identifying areas for focusing its attention. There needs to be a better dialogue between the two organisations as to how they can assist each other.	17
105		Consideration should be given to whether information from incident reports involving deaths in hospital could enhance consideration of the hospital standardised mortality ratio.	17
106	**Health Protection Agency** Coordination and publication of providers' information on healthcare associated infections	The Health Protection Agency and its successor, should coordinate the collection, analysis and publication of information on each provider's performance in relation to healthcare associated infections, working with the Health and Social Care Information Centre.	16

Rec. no.	Theme	Recommendation	Chapter
107	Sharing concerns	If the Health Protection Agency or its successor, or the relevant local director of public health or equivalent official, becomes concerned that a provider's management of healthcare associated infections is or may be inadequate to provide sufficient protection of patients or public safety, they should immediately inform all responsible commissioners, including the relevant regional office of the NHS Commissioning Board, the Care Quality Commission and, where relevant, Monitor, of those concerns. Sharing of such information should not be regarded as an action of last resort. It should review its procedures to ensure clarity of responsibility for taking this action.	16
108	Support for other agencies	Public Health England should review the support and training that health protection staff can offer to local authorities and other agencies in relation to local oversight of healthcare providers' infection control arrangements.	16
	Effective complaints handling Patients raising concerns about their care are entitled to: have the matter dealt with as a complaint unless they do not wish it; identification of their expectations; prompt and thorough processing; sensitive, responsive and accurate communication; effective and implemented learning; and proper and effective communication of the complaint to those responsible for providing the care.		
109		Methods of registering a comment or complaint must be readily accessible and easily understood. Multiple gateways need to be provided to patients, both during their treatment and after its conclusion, although all such methods should trigger a uniform process, generally led by the provider trust.	3
110	Lowering barriers	Actual or intended litigation should not be a barrier to the processing or investigation of a complaint at any level. It may be prudent for parties in actual or potential litigation to agree to a stay of proceedings pending the outcome of the complaint, but the duties of the system to respond to complaints should be regarded as entirely separate from the considerations of litigation.	3
111		Provider organisations must constantly promote to the public their desire to receive and learn from comments and complaints; constant encouragement should be given to patients and other service users, individually and collectively, to share their comments and criticisms with the organisation.	3
112		Patient feedback which is not in the form of a complaint but which suggests cause for concern should be the subject of investigation and response of the same quality as a formal complaint, whether or not the informant has indicated a desire to have the matter dealt with as such.	3
113	Complaints handling	The recommendations and standards suggested in the Patients Association's peer review into complaints at the Mid Staffordshire NHS Foundation Trust should be reviewed and implemented in the NHS.	3
114		Comments or complaints which describe events amounting to an adverse or serious untoward incident should trigger an investigation.	3
115	Investigations	Arms-length independent investigation of a complaint should be initiated by the provider trust where any one of the following apply: • A complaint amounts to an allegation of a serious untoward incident; • Subject matter involving clinically related issues is not capable of resolution without an expert clinical opinion; • A complaint raises substantive issues of professional misconduct or the performance of senior managers; • A complaint involves issues about the nature and extent of the services commissioned.	3

Rec. no.	Theme	Recommendation	Chapter
116	Support for complainants	Where meetings are held between complainants and trust representatives or investigators as part of the complaints process, advocates and advice should be readily available to all complainants who want those forms of support.	3
117		A facility should be available to Independent Complaints Advocacy Services advocates and their clients for access to expert advice in complicated cases.	3
118	Learning and information from complaints	Subject to anonymisation, a summary of each upheld complaint relating to patient care, in terms agreed with the complainant, and the trust's response should be published on its website. In any case where the complainant or, if different, the patient, refuses to agree, or for some other reason publication of an upheld, clinically related complaint is not possible, the summary should be shared confidentially with the Commissioner and the Care Quality Commission.	3
119		Overview and scrutiny committees and Local Healthwatch should have access to detailed information about complaints, although respect needs to be paid in this instance to the requirement of patient confidentiality.	3
120		Commissioners should require access to all complaints information as and when complaints are made, and should receive complaints and their outcomes on as near a real-time basis as possible. This means commissioners should be required by the NHS Commissioning Board to undertake the support and oversight role of GPs in this area, and be given the resources to do so.	3
121		The Care Quality Commission should have a means of ready access to information about the most serious complaints. Their local inspectors should be charged with informing themselves of such complaints and the detail underlying them.	3
122	Handling large-scale complaints	Large-scale failures of clinical service are likely to have in common a need for: • Provision of prompt advice, counselling and support to very distressed and anxious members of the public; • Swift identification of persons of independence, authority and expertise to lead investigations and reviews; • A procedure for the recruitment of clinical and other experts to review cases; • A communications strategy to inform and reassure the public of the processes being adopted; • Clear lines of responsibility and accountability for the setting up and oversight of such reviews. Such events are of sufficient rarity and importance, and requiring of coordination of the activities of multiple organisations, that the primary responsibility should reside in the National Quality Board.	3
	Commissioning for standards		
123	Responsibility for monitoring delivery of standards and quality	GPs need to undertake a monitoring role on behalf of their patients who receive acute hospital and other specialist services. They should be an independent, professionally qualified check on the quality of service, in particular in relation to an assessment of outcomes. They need to have internal systems enabling them to be aware of patterns of concern, so that they do not merely treat each case on its individual merits. They have a responsibility to all their patients to keep themselves informed of the standard of service available at various providers in order to make patients' choice reality. A GP's duty to a patient does not end on referral to hospital, but is a continuing relationship. They will need to take this continuing partnership with their patients seriously if they are to be successful commissioners.	7

Rec. no.	Theme	Recommendation	Chapter
124	Duty to require and monitor delivery of fundamental standards	The commissioner is entitled to and should, wherever it is possible to do so, apply a fundamental safety and quality standard in respect of each item of service it is commissioning. In relation to each such standard, it should agree a method of measuring compliance and redress for non-compliance. Commissioners should consider whether it would incentivise compliance by requiring redress for individual patients who have received sub-standard service to be offered by the provider. These must be consistent with fundamental standards enforceable by the Care Quality Commission.	7
125	Responsibility for requiring and monitoring delivery of enhanced standards	In addition to their duties with regard to the fundamental standards, commissioners should be enabled to promote improvement by requiring compliance with enhanced standards or development towards higher standards. They can incentivise such improvements either financially or by other means designed to enhance the reputation and standing of clinicians and the organisations for which they work.	7
126	Preserving corporate memory	The NHS Commissioning Board and local commissioners should develop and oversee a code of practice for managing organisational transitions, to ensure the information conveyed is both candid and comprehensive. This code should cover both transitions between commissioners, for example as new clinical commissioning groups are formed, and guidance for commissioners on what they should expect to see in any organisational transitions amongst their providers.	7
127	Resources for scrutiny	The NHS Commissioning Board and local commissioners must be provided with the infrastructure and the support necessary to enable a proper scrutiny of its providers' services, based on sound commissioning contracts, while ensuring providers remain responsible and accountable for the services they provide.	7
128	Expert support	Commissioners must have access to the wide range of experience and resources necessary to undertake a highly complex and technical task, including specialist clinical advice and procurement expertise. When groups are too small to acquire such support, they should collaborate with others to do so.	7
129	Ensuring assessment and enforcement of fundamental standards through contracts	In selecting indicators and means of measuring compliance, the principal focus of commissioners should be on what is reasonably necessary to safeguard patients and to ensure that at least fundamental safety and quality standards are maintained. This requires close engagement with patients, past, present and potential, to ensure that their expectations and concerns are addressed.	7
130	Relative position of commissioner and provider	Commissioners – not providers – should decide what they want to be provided. They need to take into account what can be provided, and for that purpose will have to consult clinicians both from potential providers and elsewhere, and to be willing to receive proposals, but in the end it is the commissioner whose decision must prevail.	7
131	Development of alternative sources of provision	Commissioners need, wherever possible, to identify and make available alternative sources of provision. This may mean that commissioning has to be undertaken on behalf of consortia of commissioning groups to provide the negotiating weight necessary to achieve a negotiating balance of power with providers.	7

Rec. no.	Theme	Recommendation	Chapter
132	Monitoring tools	Commissioners must have the capacity to monitor the performance of every commissioning contract on a continuing basis during the contract period: • Such monitoring may include requiring quality information generated by the provider. • Commissioners must also have the capacity to undertake their own (or independent) audits, inspections, and investigations. These should, where appropriate, include investigation of individual cases and reviews of groups of cases. • The possession of accurate, relevant, and useable information from which the safety and quality of a service can be ascertained is the vital key to effective commissioning, as it is to effective regulation. • Monitoring needs to embrace both compliance with the fundamental standards and with any enhanced standards adopted. In the case of the latter, they will be the only source of monitoring, leaving the healthcare regulator to focus on fundamental standards.	7
133	Role of commissioners in complaints	Commissioners should be entitled to intervene in the management of an individual complaint on behalf of the patient where it appears to them it is not being dealt with satisfactorily, while respecting the principle that it is the provider who has primary responsibility to process and respond to complaints about its services.	7
134	Role of commissioners in provision of support for complainants	Consideration should be given to whether commissioners should be given responsibility for commissioning patients' advocates and support services for complaints against providers.	7
135	Public accountability of commissioners and public engagement	Commissioners should be accountable to their public for the scope and quality of services they commission. Acting on behalf of the public requires their full involvement and engagement: • There should be a membership system whereby eligible members of the public can be involved in and contribute to the work of the commissioners. • There should be lay members of the commissioner's board. • Commissioners should create and consult with patient forums and local representative groups. Individual members of the public (whether or not members) must have access to a consultative process so their views can be taken into account. • There should be regular surveys of patients and the public more generally. • Decision-making processes should be transparent: decision-making bodies should hold public meetings. Commissioners need to create and maintain a recognisable identity which becomes a familiar point of reference for the community.	7
136		Commissioners need to be recognisable public bodies, visibly acting on behalf of the public they serve and with a sufficient infrastructure of technical support. Effective local commissioning can only work with effective local monitoring, and that cannot be done without knowledgeable and skilled local personnel engaging with an informed public.	7
137	Intervention and sanctions for substandard or unsafe services	Commissioners should have powers of intervention where substandard or unsafe services are being provided, including requiring the substitution of staff or other measures necessary to protect patients from the risk of harm. In the provision of the commissioned services, such powers should be aligned with similar powers of the regulators so that both commissioners and regulators can act jointly, but with the proviso that either can act alone if the other declines to do so. The powers should include the ability to order a provider to stop provision of a service.	7

Rec. no.	Theme	Recommendation	Chapter
	Local scrutiny		
138		Commissioners should have contingency plans with regard to the protection of patients from harm, where it is found that they are at risk from substandard or unsafe services.	7
	Performance management and strategic oversight		
139	The need to put patients first at all times	The first priority for any organisation charged with responsibility for performance management of a healthcare provider should be ensuring that fundamental patient safety and quality standards are being met. Such an organisation must require convincing evidence to be available before accepting that such standards are being complied with.	8
140	Performance managers working constructively with regulators	Where concerns are raised that such standards are not being complied with, a performance management organisation should share, wherever possible, all relevant information with the relevant regulator, including information about its judgement as to the safety of patients of the healthcare provider.	8
141	Taking responsibility for quality	Any differences of judgement as to immediate safety concerns between a performance manager and a regulator should be discussed between them and resolved where possible, but each should recognise its retained individual responsibility to take whatever action within its power is necessary in the interests of patient safety.	8
142	Clear lines of responsibility supported by good information flows	For an organisation to be effective in performance management, there must exist unambiguous lines of referral and information flows, so that the performance manager is not in ignorance of the reality.	8
143	Clear metrics on quality	Metrics need to be established which are relevant to the quality of care and patient safety across the service, to allow norms to be established so that outliers or progression to poor performance can be identified and accepted as needing to be fixed.	8
144	Need for ownership of quality metrics at a strategic level	The NHS Commissioning Board should ensure the development of metrics on quality and outcomes of care for use by commissioners in managing the performance of providers, and retain oversight of these through its regional offices, if appropriate.	8
	Patient, public and local scrutiny		
145	Structure of Local Healthwatch	There should be a consistent basic structure for Local Healthwatch throughout the country, in accordance with the principles set out in *Chapter 6: Patient and public local involvement and scrutiny*.	6
146	Finance and oversight of Local Healthwatch	Local authorities should be required to pass over the centrally provided funds allocated to its Local Healthwatch, while requiring the latter to account to it for its stewardship of the money. Transparent respect for the independence of Local Healthwatch should not be allowed to inhibit a responsible local authority – or Healthwatch England as appropriate – intervening.	6
147	Coordination of local public scrutiny bodies	Guidance should be given to promote the coordination and cooperation between Local Healthwatch, Health and Wellbeing Boards, and local government scrutiny committees.	6
148	Training	The complexities of the health service are such that proper training must be available to the leadership of Local Healthwatch as well as, when the occasion arises, expert advice.	6
149	Expert assistance	Scrutiny committees should be provided with appropriate support to enable them to carry out their scrutiny role, including easily accessible guidance and benchmarks.	6

Rec. no.	Theme	Recommendation	Chapter
150	Inspection powers	Scrutiny committees should have powers to inspect providers, rather than relying on local patient involvement structures to carry out this role, or should actively work with those structures to trigger and follow up inspections where appropriate, rather than receiving reports without comment or suggestions for action.	6
151	Complaints to MPs	MPs are advised to consider adopting some simple system for identifying trends in the complaints and information they received from constituents. They should also consider whether individual complaints imply concerns of wider significance than the impact on one individual patient.	6
	Medical training and education		
152	Medical training	Any organisation which in the course of a review, inspection or other performance of its duties, identifies concerns potentially relevant to the acceptability of training provided by a healthcare provider, must be required to inform the relevant training regulator of those concerns.	18
153		The Secretary of State should by statutory instrument specify all medical education and training regulators as relevant bodies for the purpose of their statutory duty to cooperate. Information sharing between the deanery, commissioners, the General Medical Council, the Care Quality Commission and Monitor with regard to patient safety issues must be reviewed to ensure that each organisation is made aware of matters of concern relevant to their responsibilities.	18
154		The Care Quality Commission and Monitor should develop practices and procedures with training regulators and bodies responsible for the commissioning and oversight of medical training to coordinate their oversight of healthcare organisations which provide regulated training.	18
155		The General Medical Council should set out a standard requirement for routine visits to each local education provider, and programme in accordance with the following principles: • The Postgraduate Dean should be responsible for managing the process at the level of the Local Educational Training Board, as part of overall deanery functions. • The Royal Colleges should be enlisted to support such visits and to provide the relevant specialist expertise where required. • There should be lay or patient representation on visits to ensure that patient interests are maintained as the priority. • Such visits should be informed by all other sources of information and, if relevant, coordinated with the work of the Care Quality Commission and other forms of review. The Department of Health should provide appropriate resources to ensure that an effective programme of monitoring training by visits can be carried out. All healthcare organisations must be required to release healthcare professionals to support the visits programme. It should also be recognised that the benefits in professional development and dissemination of good practice are of significant value.	18
156		The system for approving and accrediting training placement providers and programmes should be configured to apply the principles set out above.	18

Rec. no.	Theme	Recommendation	Chapter
157	Matters to be reported to the General Medical Council	The General Medical Council should set out a clear statement of what matters; deaneries are required to report to the General Medical Council either routinely or as they arise. Reports should include a description of all relevant activity and findings and not be limited to exceptional matters of perceived non-compliance with standards. Without a compelling and recorded reason, no professional in a training organisation interviewed by a regulator in the course of an investigation should be bound by a requirement of confidentiality not to report the existence of an investigation, and the concerns raised by or to the investigation with his own organisation.	18
158	Training and training establishments as a source of safety information	The General Medical Council should amend its standards for undergraduate medical education to include a requirement that providers actively seek feedback from students and tutors on compliance by placement providers with minimum standards of patient safety and quality of care, and should generally place the highest priority on the safety of patients.	18
159		Surveys of medical students and trainees should be developed to optimise them as a source of feedback of perceptions of the standards of care provided to patients. The General Medical Council should consult the Care Quality Commission in developing the survey and routinely share information obtained with healthcare regulators.	18
160		Proactive steps need to be taken to encourage openness on the part of trainees and to protect them from any adverse consequences in relation to raising concerns.	18
161		Training visits should make an important contribution to the protection of patients: • Obtaining information directly from trainees should remain a valuable source of information – but it should not be the only method used. • Visits to, and observation of, the actual training environment would enable visitors to detect poor practice from which both patients and trainees should be sheltered. • The opportunity can be taken to share and disseminate good practice with trainers and management. Visits of this nature will encourage the transparency that is so vital to the preservation of minimum standards.	18
162		The General Medical Council should in the course of its review of its standards and regulatory process ensure that the system of medical training and education maintains as its first priority the safety of patients. It should also ensure that providers of clinical placements are unable to take on students or trainees in areas which do not comply with fundamental patient safety and quality standards. Regulators and deaneries should exercise their own independent judgement as to whether such standards have been achieved and if at any stage concerns relating to patient safety are raised to the, must take appropriate action to ensure these concerns are properly addressed.	18
163	Safe staff numbers and skills	The General Medical Council's system of reviewing the acceptability of the provision of training by healthcare providers must include a review of the sufficiency of the numbers and skills of available staff for the provision of training and to ensure patient safety in the course of training.	18
164	Approved Practice Settings	The Department of Health and the General Medical Council should review whether the resources available for regulating Approved Practice Setting are adequate and, if not, make arrangements for the provision of the same. Consideration should be given to empowering the General Medical Council to charge organisations a fee for approval.	18
165		The General Medical Council should immediately review its approved practice settings criteria with a view to recognition of the priority to be given to protecting patients and the public.	18

Rec. no.	Theme	Recommendation	Chapter
166		The General Medical Council should in consultation with patient interest groups and the public immediately review its procedures for assuring compliance with its approved practice settings criteria with a view in particular to provision for active exchange of relevant information with the healthcare systems regulator, coordination of monitoring processes with others required for medical education and training, and receipt of relevant information from registered practitioners of their current experience in approved practice settings approved establishments.	18
167		The Department of Health and the General Medical Council should review the powers available to the General Medical Council in support of assessment and monitoring of approved practice settings establishments with a view to ensuring that the General Medical Council (or if considered to be more appropriate, the healthcare systems regulator) has the power to inspect establishments, either itself or by an appointed entity on its behalf, and to require the production of relevant information.	18
168		The Department of Health and the General Medical Council should consider making the necessary statutory (and regulatory changes) to incorporate the approved practice settings scheme into the regulatory framework for post graduate training.	18
169	Role of the Department of Health and the National Quality Board	The Department of Health, through the National Quality Board, should ensure that procedures are put in place for facilitating the identification of patient safety issues by training regulators and cooperation between them and healthcare systems regulators.	18
170	Health Education England	Health Education England should have a medically qualified director of medical education and a lay patient representative on its board.	18
171	Deans	All Local Education and Training Boards should have a post of medically qualified postgraduate dean responsible for all aspects of postgraduate medical education.	18
172	Proficiency in the English language	The Government should consider urgently the introduction of a common requirement of proficiency in communication in the English language with patients and other persons providing healthcare to the standard required for a registered medical practitioner to assume professional responsibility for medical treatment of an English-speaking patient.	18
	Openness, transparency and candour Openness – enabling concerns and complaints to be raised freely without fear and questions asked to be answered. Transparency – allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators. Candour – any patient harmed by the provision of a healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it.		
173	**Principles of openness, transparency and candour**	Every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public, and organisational and personal interests must never be allowed to outweigh the duty to be honest, open and truthful.	22
174	Candour about harm	Where death or serious harm has been or may have been caused to a patient by an act or omission of the organisation or its staff, the patient (or any lawfully entitled personal representative or other authorised person) should be informed of the incident, given full disclosure of the surrounding circumstances and be offered an appropriate level of support, whether or not the patient or representative has asked for this information.	22

Rec. no.	Theme	Recommendation	Chapter
175		Full and truthful answers must be given to any question reasonably asked about his or her past or intended treatment by a patient (or, if deceased, to any lawfully entitled personal representative).	22
176	Openness with regulators	Any statement made to a regulator or a commissioner in the course of its statutory duties must be completely truthful and not misleading by omission.	22
177	Openness in public statements	Any public statement made by a healthcare organisation about its performance must be truthful and not misleading by omission.	22
178	**Implementation of the duty** Ensuring consistency of obligations under the duty of openness, transparency and candour	The NHS Constitution should be revised to reflect the changes recommended with regard to a duty of openness, transparency and candour, and all organisations should review their contracts of employment, policies and guidance to ensure that, where relevant, they expressly include and are consistent with above principles and these recommendations.	22
179	Restrictive contractual clauses	"Gagging clauses" or non disparagement clauses should be prohibited in the policies and contracts of all healthcare organisations, regulators and commissioners; insofar as they seek, or appear, to limit bona fide disclosure in relation to public interest issues of patient safety and care.	22
180	Candour about incidents	Guidance and policies should be reviewed to ensure that they will lead to compliance with *Being Open*, the guidance published by the National Patient Safety Agency.	22
181	**Enforcement of the duty** Statutory duties of candour in relation to harm to patients	A statutory obligation should be imposed to observe a duty of candour: • On healthcare providers who believe or suspect that treatment or care provided by it to a patient has caused death or serious injury to a patient to inform that patient or other duly authorised person as soon as is practicable of that fact and thereafter to provide such information and explanation as the patient reasonably may request; • On registered medical practitioners and registered nurses and other registered professionals who believe or suspect that treatment or care provided to a patient by or on behalf of any healthcare provider by which they are employed has caused death or serious injury to the patient to report their belief or suspicion to their employer as soon as is reasonably practicable. The provision of information in compliance with this requirement should not of itself be evidence or an admission of any civil or criminal liability, but non-compliance with the statutory duty should entitle the patient to a remedy.	22
182	Statutory duty of openness and transparency	There should be a statutory duty on all directors of healthcare organisations to be truthful in any information given to a healthcare regulator or commissioner, either personally or on behalf of the organisation, where given in compliance with a statutory obligation on the organisation to provide it.	22
183	Criminal liability	It should be made a criminal offence for any registered medical practitioner, or nurse, or allied health professional or director of an authorised or registered healthcare organisation: • Knowingly to obstruct another in the performance of these statutory duties; • To provide information to a patient or nearest relative intending to mislead them about such an incident; • Dishonestly to make an untruthful statement to a commissioner or regulator knowing or believing that they are likely to rely on the statement in the performance of their duties.	22

Rec. no.	Theme	Recommendation	Chapter
184	Enforcement by the Care Quality Commission	Observance of the duty should be policed by the Care Quality Commission, which should have powers in the last resort to prosecute in cases of serial non-compliance or serious and wilful deception. The Care Quality Commission should be supported by monitoring undertaken by commissioners and others.	22
	Nursing		
185	Focus on culture of caring	There should be an increased focus in nurse training, education and professional development on the practical requirements of delivering compassionate care in addition to the theory. A system which ensures the delivery of proper standards of nursing requires: • Selection of recruits to the profession who evidence the: – Possession of the appropriate values, attitudes and behaviours; – Ability and motivation to enable them to put the welfare of others above their own interests; – Drive to maintain, develop and improve their own standards and abilities; – Intellectual achievements to enable them to acquire through training the necessary technical skills; • Training and experience in delivery of compassionate care; • Leadership which constantly reinforces values and standards of compassionate care; • Involvement in, and responsibility for, the planning and delivery of compassionate care; • Constant support and incentivisation which values nurses and the work they do through: – Recognition of achievement; – Regular, comprehensive feedback on performance and concerns; – Encouraging them to report concerns and to give priority to patient well-being.	23
186	Practical hands-on training and experience	Nursing training should be reviewed so that sufficient practical elements are incorporated to ensure that a consistent standard is achieved by all trainees throughout the country. This requires national standards.	23
187		There should be a national entry-level requirement that student nurses spend a minimum period of time, at least three months, working on the direct care of patients under the supervision of a registered nurse. Such experience should include direct care of patients, ideally including the elderly, and involve hands-on physical care. Satisfactory completion of this direct care experience should be a pre-condition to continuation in nurse training. Supervised work of this type as a healthcare support worker should be allowed to count as an equivalent. An alternative would be to require candidates for qualification for registration to undertake a minimum period of work in an approved healthcare support worker post involving the delivery of such care.	23
188	Aptitude test for compassion and caring	The Nursing and Midwifery Council, working with universities, should consider the introduction of an aptitude test to be undertaken by aspirant registered nurses at entry into the profession, exploring, in particular, candidates' attitudes towards caring, compassion and other necessary professional values.	23
189	Consistent training	The Nursing and Midwifery Council and other professional and academic bodies should work towards a common qualification assessment/examination.	23
190	National standards	There should be national training standards for qualification as a registered nurse to ensure that newly qualified nurses are competent to deliver a consistent standard of the fundamental aspects of compassionate care.	23
191	Recruitment for values and commitment	Healthcare employers recruiting nursing staff, whether qualified or unqualified, should assess candidates' values, attitudes and behaviours towards the well-being of patients and their basic care needs, and care providers should be required to do so by commissioning and regulatory requirements.	23
192	Strong nursing voice	The Department of Health and Nursing and Midwifery Council should introduce the concept of a Responsible Officer for nursing, appointed by and accountable to, the Nursing and Midwifery Council.	23

Rec. no.	Theme	Recommendation	Chapter
193	Standards for appraisal and support	Without introducing a revalidation scheme immediately, the Nursing and Midwifery Council should introduce common minimum standards for appraisal and support with which responsible officers would be obliged to comply. They could be required to report to the Nursing and Midwifery Council on their performance on a regular basis.	23
194		As part of a mandatory annual performance appraisal, each Nurse, regardless of workplace setting, should be required to demonstrate in their annual learning portfolio an up-to-date knowledge of nursing practice and its implementation. Alongside developmental requirements, this should contain documented evidence of recognised training undertaken, including wider relevant learning. It should also demonstrate commitment, compassion and caring for patients, evidenced by feedback from patients and families on the care provided by the nurse. This portfolio and each annual appraisal should be made available to the Nursing and Midwifery Council, if requested, as part of a nurse's revalidation process. At the end of each annual assessment, the appraisal and portfolio should be signed by the nurse as being an accurate and true reflection and be countersigned by their appraising manager as being such.	23
195	Nurse leadership	Ward nurse managers should operate in a supervisory capacity, and not be office-bound or expected to double up, except in emergencies as part of the nursing provision on the ward. They should know about the care plans relating to every patient on his or her ward. They should make themselves visible to patients and staff alike, and be available to discuss concerns with all, including relatives. Critically, they should work alongside staff as a role model and mentor, developing clinical competencies and leadership skills within the team. As a corollary, they would monitor performance and deliver training and/or feedback as appropriate, including a robust annual appraisal.	23
196		The Knowledge and Skills Framework should be reviewed with a view to giving explicit recognition to nurses' demonstrations of commitment to patient care and, in particular, to the priority to be accorded to dignity and respect, and their acquisition of leadership skills.	23
197		Training and continuing professional development for nurses should include leadership training at every level from student to director. A resource for nurse leadership training should be made available for all NHS healthcare provider organisations that should be required under commissioning arrangements by those buying healthcare services to arrange such training for appropriate staff.	23
198	Measuring cultural health	Healthcare providers should be encouraged by incentives to develop and deploy reliable and transparent measures of the cultural health of front-line nursing workplaces and teams, which build on the experience and feedback of nursing staff using a robust methodology, such as the "cultural barometer".	23
199	Key nurses	Each patient should be allocated for each shift a named key nurse responsible for coordinating the provision of the care needs for each allocated patient. The named key nurse on duty should, whenever possible, be present at every interaction between a doctor and an allocated patient.	23
200		Consideration should be given to the creation of a status of Registered Older Person's Nurse.	23
201	Strengthening the nursing professional voice	The Royal College of Nursing should consider whether it should formally divide its "Royal College" functions and its employee representative/trade union functions between two bodies rather than behind internal "Chinese walls".	23
202		Recognition of the importance of nursing representation at provider level should be given by ensuring that adequate time is allowed for staff to undertake this role, and employers and unions must regularly review the adequacy of the arrangements in this regard.	23

Rec. no.	Theme	Recommendation	Chapter
203		A forum for all directors of nursing from both NHS and independent sector organisations should be formed to provide a means of coordinating the leadership of the nursing profession.	23
204		All healthcare providers and commissioning organisations should be required to have at least one executive director who is a registered nurse, and should be encouraged to consider recruiting nurses as non-executive directors.	23
205		Commissioning arrangements should require the boards of provider organisations to seek and record the advice of its nursing director on the impact on the quality of care and patient safety of any proposed major change to nurse staffing arrangements or provision facilities, and to record whether they accepted or rejected the advice, in the latter case recording its reasons for doing so.	23
206		The effectiveness of the newly positioned office of Chief Nursing Officer should be kept under review to ensure the maintenance of a recognised leading representative of the nursing profession as a whole, able and empowered to give independent professional advice to the Government on nursing issues of equivalent authority to that provided by the Chief Medical Officer.	23
207	Strengthening identification of healthcare support workers and nurses	There should be a uniform description of healthcare support workers, with the relationship with currently registered nurses made clear by the title.	23
208		Commissioning arrangements should require provider organisations to ensure by means of identity labels and uniforms that a healthcare support worker is easily distinguishable from that of a registered nurse.	23
209	Registration of healthcare support workers	A registration system should be created under which no unregistered person should be permitted to provide for reward direct physical care to patients currently under the care and treatment of a registered nurse or a registered doctor (or who are dependent on such care by reason of disability and/or infirmity) in a hospital or care home setting. The system should apply to healthcare support workers, whether they are working for the NHS or independent healthcare providers, in the community, for agencies or as independent agents. (Exemptions should be made for persons caring for members of their own family or those with whom they have a genuine social relationship.)	23
210	Code of conduct for healthcare support workers	There should be a national code of conduct for healthcare support workers.	23
211	Training standards for healthcare support workers	There should be a common set of national standards for the education and training of healthcare support workers.	23
212		The code of conduct, education and training standards and requirements for registration for healthcare support workers should be prepared and maintained by the Nursing and Midwifery Council after due consultation with all relevant stakeholders, including the Department of Health, other regulators, professional representative organisations and the public.	23

Rec. no.	Theme	Recommendation	Chapter
213		Until such time as the Nursing and Midwifery Council is charged with the recommended regulatory responsibilities, the Department of Health should institute a nationwide system to protect patients and care receivers from harm. This system should be supported by fair due process in relation to employees in this grade who have been dismissed by employers on the grounds of a serious breach of the code of conduct or otherwise being unfit for such a post.	23
	Leadership		
214	Shared training	A leadership staff college or training system, whether centralised or regional, should be created to: provide common professional training in management and leadership to potential senior staff; promote healthcare leadership and management as a profession; administer an accreditation scheme to enhance eligibility for consideration for such roles; promote and research best leadership practice in healthcare.	24
215	Shared code of ethics	A common code of ethics, standards and conduct for senior board-level healthcare leaders and managers should be produced and steps taken to oblige all such staff to comply with the code and their employers to enforce it.	24
216	Leadership framework	The leadership framework should be improved by increasing the emphasis given to patient safety in the thinking of all in the health service. This could be done by, for example, creating a separate domain for managing safety, or by defining the service to be delivered as a safe and effective service.	24
217	Common selection criteria	A list should be drawn up of all the qualities generally considered necessary for a good and effective leader. This in turn could inform a list of competences a leader would be expected to have.	24
218	Enforcement of standards and accountability	Serious non-compliance with the code, and in particular, non-compliance leading to actual or potential harm to patients, should render board-level leaders and managers liable to be found not to be fit and proper persons to hold such positions by a fair and proportionate procedure, with the effect of disqualifying them from holding such positions in future.	24
219	A regulator as an alternative	An alternative option to enforcing compliance with a management code of conduct, with the risk of disqualification, would be to set up an independent professional regulator. The need for this would be greater if it were thought appropriate to extend a regulatory requirement to a wider range of managers and leaders. The proportionality of such a step could be better assessed after reviewing the experience of a licensing provision for directors.	24
220	Accreditation	A training facility could provide the route through which an accreditation scheme could be organised. Although this might be a voluntary scheme, at least initally, the objective should be to require all leadership posts to be filled by persons who experience some shared training and obtain the relevant accreditation, enhancing the spread of the common culture and providing the basis for a regulatory regime.	24
221	Ensuring common standards of competence and compliance	Consideration should be given to ensuring that there is regulatory oversight of the competence and compliance with appropriate standards by the boards of health service bodies which are not foundation trusts, of equivalent rigour to that applied to foundation trusts.	24
	Professional regulation of fitness to practise		
222	**General Medical Council** Systemic investigation where needed	The General Medical Council should have a clear policy about the circumstances in which a generic complaint or report ought to be made to it, enabling a more proactive approach to monitoring fitness to practise.	12

Rec. no.	Theme	Recommendation	Chapter
223	Enhanced resources	If the General Medical Council is to be effective in looking into generic complaints and information it will probably need either greater resources, or better cooperation with the Care Quality Commission and other organisations such as the Royal Colleges to ensure that it is provided with the appropriate information.	12
224	Information sharing	Steps must be taken to systematise the exchange of information between the Royal Colleges and the General Medical Council, and to issue guidance for use by employers of doctors to the same effect.	12
225	Peer reviews	The General Medical Council should have regard to the possibility of commissioning peer reviews pursuant to section 35 of the Medical Act 1983 where concerns are raised in a generic way, in order to be advised whether there are individual concerns. Such reviews could be jointly commissioned with the Care Quality Commission in appropriate cases.	12
226	**Nursing and Midwifery Council** Investigation of systemic concerns	To act as an effective regulator of nurse managers and leaders, as well as more front-line nurses, the Nursing and Midwifery Council needs to be equipped to look at systemic concerns as well as individual ones. It must be enabled to work closely with the systems regulators and to share their information and analyses on the working of systems in organisations in which nurses are active. It should not have to wait until a disaster has occurred to intervene with its fitness to practise procedures. Full access to the Care Quality Commission information in particular is vital.	12
227		The Nursing and Midwifery Council needs to have its own internal capacity to assess systems and launch its own proactive investigations where it becomes aware of concerns which may give rise to nursing fitness to practise issues. It may decide to seek the cooperation of the Care Quality Commission, but as an independent regulator it must be empowered to act on its own if it considers it necessary in the public interest. This will require resources in terms of appropriately expert staff, data systems and finance. Given the power of the registrar to refer cases without a formal third party complaint, it would not appear that a change of regulation is necessary, but this should be reviewed.	12
228	Administrative reform	It is of concern that the administration of the Nursing and Midwifery Council, which has not been examined by this Inquiry, is still found by other reviews to be wanting. It is imperative in the public interest that this is remedied urgently. Without doing so, there is a danger that the regulatory gap between the Nursing and Midwifery Council and the Care Quality Commission will widen rather than narrow.	12
229	Revalidation	It is highly desirable that the Nursing and Midwifery Council introduces a system of revalidation similar to that of the General Medical Council, as a means of reinforcing the status and competence of registered nurses, as well as providing additional protection to the public. It is essential that the Nursing and Midwifery Council has the resources and the administrative and leadership skills to ensure that this does not detract from its existing core function of regulating fitness to practise of registered nurses.	12
230	Profile	The profile of the Nursing and Midwifery Council needs to be raised with the public, who are the prime and most valuable source of information about the conduct of nurses. All patients should be informed, by those providing treatment or care, of the existence and role of the Nursing and Midwifery Council, together with contact details. The Nursing and Midwifery Council itself needs to undertake more by way of public promotion of its functions.	12
231	Coordination with internal procedures	It is essential that, so far as practicable, Nursing and Midwifery Council procedures do not obstruct the progress of internal disciplinary action in providers. In most cases it should be possible, through cooperation, to allow both to proceed in parallel. This may require a review of employment disciplinary procedures, to make it clear that the employer is entitled to proceed even if there are pending Nursing and Midwifery Council proceedings.	12

Rec. no.	Theme	Recommendation	Chapter
232	Employment liaison officers	The Nursing and Midwifery Council could consider a concept of employment liaison officers, similar to that of the General Medical Council, to provide support to directors of nursing. If this is impractical, a support network of senior nurse leaders will have to be engaged in filling this gap.	12
233	**For joint action** Profile	While both the General Medical Council and the Nursing and Midwifery Council have highly informative internet sites, both need to ensure that patients and other service users are made aware at the point of service provision of their existence, their role and their contact details.	12
234	Cooperation with the Care Quality Commission	Both the General Medical Council and Nursing and Midwifery Council must develop closer working relationships with the Care Quality Commission – in many cases there should be joint working to minimise the time taken to resolve issues and maximise the protection afforded to the public.	12
235	Joint proceedings	The Professional Standards Authority for Health and Social Care (PSA) (formerly the Council for Healthcare Regulatory Excellence), together with the regulators under its supervision, should seek to devise procedures for dealing consistently and in the public interest with cases arising out of the same event or series of events but involving professionals regulated by more than one body. While it would require new regulations, consideration should be given to the possibility of moving towards a common independent tribunal to determine fitness to practise issues and sanctions across the healthcare professional field.	12
	Caring for the elderly Approaches applicable to all patients but requiring special attention for the elderly		
236	Identification of who is responsible for the patient	Hospitals should review whether to reinstate the practice of identifying a senior clinician who is in charge of a patient's case, so that patients and their supporters are clear who is in overall charge of a patient's care.	25
237	Teamwork	There needs to be effective teamwork between all the different disciplines and services that together provide the collective care often required by an elderly patient; the contribution of cleaners, maintenance staff, and catering staff also needs to be recognised and valued.	25
238	Communication with and about patients	Regular interaction and engagement between nurses and patients and those close to them should be systematised through regular ward rounds: • All staff need to be enabled to interact constructively, in a helpful and friendly fashion, with patients and visitors. • Where possible, wards should have areas where more mobile patients and their visitors can meet in relative privacy and comfort without disturbing other patients. • The NHS should develop a greater willingness to communicate by email with relatives. • The currently common practice of summary discharge letters followed up some time later with more substantive ones should be reconsidered. • Information about an older patient's condition, progress and care and discharge plans should be available and shared with that patient and, where appropriate, those close to them, who must be included in the therapeutic partnership to which all patients are entitled.	25
239	Continuing responsibility for care	The care offered by a hospital should not end merely because the patient has surrendered a bed – it should never be acceptable for patients to be discharged in the middle of the night, still less so at any time without absolute assurance that a patient in need of care will receive it on arrival at the planned destination. Discharge areas in hospital need to be properly staffed and provide continued care to the patient.	25

Rec. no.	Theme	Recommendation	Chapter
240	Hygiene	All staff and visitors need to be reminded to comply with hygiene requirements. Any member of staff, however junior, should be encouraged to remind anyone, however senior, of these.	25
241	Provision of food and drink	The arrangements and best practice for providing food and drink to elderly patients require constant review, monitoring and implementation.	25
242	Medicines administration	In the absence of automatic checking and prompting, the process of the administration of medication needs to be overseen by the nurse in charge of the ward, or his/her nominated delegate. A frequent check needs to be done to ensure that all patients have received what they have been prescribed and what they need. This is particularly the case when patients are moved from one ward to another, or they are returned to the ward after treatment.	25
243	Recording of routine observations	The recording of routine observations on the ward should, where possible, be done automatically as they are taken, with results being immediately accessible to all staff electronically in a form enabling progress to be monitored and interpreted. If this cannot be done, there needs to be a system whereby ward leaders and named nurses are responsible for ensuring that the observations are carried out and recorded.	25
	Information		
244	Common information practices, shared data and electronic records	There is a need for all to accept common information practices, and to feed performance information into shared databases for monitoring purposes. The following principles should be applied in considering the introduction of electronic patient information systems: • Patients need to be granted user friendly, real time and retrospective access to read their records, and a facility to enter comments. They should be enabled to have a copy of records in a form useable by them, if they wish to have one. If possible, the summary care record should be made accessible in this way. • Systems should be designed to include prompts and defaults where these will contribute to safe and effective care, and to accurate recording of information on first entry. • Systems should include a facility to alert supervisors where actions which might be expected have not occurred, or where likely inaccuracies have been entered. • Systems should, where practicable and proportionate, be capable of collecting performance management and audit information automatically, appropriately anonymised direct from entries, to avoid unnecessary duplication of input. • Systems must be designed by healthcare professionals in partnership with patient groups to secure maximum professional and patient engagement in ensuring accuracy, utility and relevance, both to the needs of the individual patients and collective professional, managerial and regulatory requirements. Systems must be capable of reflecting changing needs and local requirements over and above nationally required minimum standards.	26
245	Board accountability	Each provider organisation should have a board level member with responsibility for information.	26
246	Comparable quality accounts	Department of Health/the NHS Commissioning Board/regulators should ensure that provider organisations publish in their annual quality accounts information in a common form to enable comparisons to be made between organisations, to include a minimum of prescribed information about their compliance with fundamental and other standards, their proposals for the rectification of any non-compliance and statistics on mortality and other outcomes. Quality accounts should be required to contain the observations of commissioners, overview and scrutiny committees, and Local Healthwatch.	26
247	Accountability for quality accounts	Healthcare providers should be required to lodge their quality accounts with all organisations commissioning services from them, Local Healthwatch, and all systems regulators.	26

Rec. no.	Theme	Recommendation	Chapter
248		Healthcare providers should be required to have their quality accounts independently audited. Auditors should be given a wider remit enabling them to use their professional judgement in examining the reliability of all statements in the accounts.	26
249		Each quality account should be accompanied by a declaration signed by all directors in office at the date of the account certifying that they believe the contents of the account to be true, or alternatively a statement of explanation as to the reason any such director is unable or has refused to sign such a declaration.	26
250		It should be a criminal offence for a director to sign a declaration of belief that the contents of a quality account are true if it contains a misstatement of fact concerning an item of prescribed information which he/she does not have reason to believe is true at the time of making the declaration.	26
251	Regulatory oversight of quality accounts	The Care Quality Commission and/or Monitor should keep the accuracy, fairness and balance of quality accounts under review and should be enabled to require corrections to be issued where appropriate. In the event of an organisation failing to take that action, the regulator should be able to issue its own statement of correction.	26
252	Access to data	It is important that the appropriate steps are taken to enable properly anonymised data to be used for managerial and regulatory purposes.	26
253	Access to quality and risk profile	The information behind the quality and risk profile – as well as the ratings and methodology – should be placed in the public domain, as far as is consistent with maintaining any legitimate confidentiality of such information, together with appropriate explanations to enable the public to understand the limitations of this tool.	26
254	Access for public and patient comments	While there are likely to be many different gateways offered through which patient and public comments can be made, to avoid confusion, it would be helpful for there to be consistency across the country in methods of access, and for the output to be published in a manner allowing fair and informed comparison between organisations.	26
255	Using patient feedback	Results and analysis of patient feedback including qualitative information need to be made available to all stakeholders in as near "real time" as possible, even if later adjustments have to be made.	26
256	Follow up of patients	A proactive system for following up patients shortly after discharge would not only be good "customer service", it would probably provide a wider range of responses and feedback on their care.	26
257	Role of the Health and Social Care Information Centre	The Information Centre should be tasked with the independent collection, analysis, publication and oversight of healthcare information in England, or, with the agreement of the devolved governments, the United Kingdom. The information functions previously held by the National Patient Safety Agency should be transferred to the NHS Information Centre if made independent.	26
258		The Information Centre should continue to develop and maintain learning, standards and consensus with regard to information methodologies, with particular reference to comparative performance statistics.	26
259		The Information Centre, in consultation with the Department of Health, the NHS Commissioning Board and the Parliamentary and Health Service Ombudsman, should develop a means of publishing more detailed breakdowns of clinically related complaints.	26
260	Information standards	The standards applied to statistical information about serious untoward incidents should be the same as for any other healthcare information and in particular the principles around transparency and accessibility. It would, therefore, be desirable for the data to be supplied to, and processed by, the Information Centre and, through them, made publicly available in the same way as other quality related information.	26

Rec. no.	Theme	Recommendation	Chapter
261		The Information Centre should be enabled to undertake more detailed statistical analysis of its own than currently appears to be the case.	26
262	Enhancing the use, analysis and dissemination of healthcare information	All healthcare provider organisations, in conjunction with their healthcare professionals, should develop and maintain systems which give them: • Effective real-time information on the performance of each of their services against patient safety and minimum quality standards; • Effective real-time information of the performance of each of their consultants and specialist teams in relation to mortality, morbidity, outcome and patient satisfaction. In doing so, they should have regard, in relation to each service, to best practice for information management of that service as evidenced by recommendations of the Information Centre, and recommendations of specialist organisations such as the medical Royal Colleges. The information derived from such systems should, to the extent practicable, be published and in any event made available in full to commissioners and regulators, on request, and with appropriate explanation, and to the extent that is relevant to individual patients, to assist in choice of treatment.	26
263		It must be recognised to be the professional duty of all healthcare professionals to collaborate in the provision of information required for such statistics on the efficacy of treatment in specialties.	26
264		In the case of each specialty, a programme of development for statistics on the efficacy of treatment should be prepared, published, and subjected to regular review.	26
265		The Department of Health, the Information Centre and the Care Quality Commission should engage with each representative specialty organisation in order to consider how best to develop comparative statistics on the efficacy of treatment in that specialty, for publication and use in performance oversight, revalidation, and the promotion of patient knowledge and choice.	26
266		In designing the methodology for such statistics and their presentation, the Department of Health, the Information Centre, the Care Quality Commission and the specialty organisations should seek and have regard to the views of patient groups and the public about the information needed by them.	26
267		All such statistics should be made available online and accessible through provider websites, as well as other gateways such as the Care Quality Commission.	26
268	Resources	Resources must be allocated to and by provider organisations to enable the relevant data to be collected and forwarded to the relevant central registry.	26
269	Improving and assuring accuracy	The only practical way of ensuring reasonable accuracy is vigilant auditing at local level of the data put into the system. This is important work, which must be continued and where possible improved.	26
270		There is a need for a review by the Department of Health, the Information Centre and the UK Statistics Authority of the patient outcome statistics, including hospital mortality and other outcome indicators. In particular, there could be benefit from consideration of the extent to which these statistics can be published in a form more readily useable by the public.	26
271		To the extent that summary hospital-level mortality indicators are not already recognised as national or official statistics, the Department of Health and the Health and Social Care Information Centre should work towards establishing such status for them or any successor hospital mortality figures, and other patient outcome statistics, including reports showing provider-level detail.	26

Rec. no.	Theme	Recommendation	Chapter
272		There is a demonstrable need for an accreditation system to be available for healthcare-relevant statistical methodologies. The power to create an accreditation scheme has been included in the Health and Social Care Act 2012, it should be used as soon as practicable.	26
	Coroners and inquests Making more of the coronial process in healthcare-related deaths		
273	Information to coroners	The terms of authorisation, licensing and registration and any relevant guidance should oblige healthcare providers to provide all relevant information to enable the coroner to perform his function, unless a director is personally satisfied that withholding the information is justified in the public interest.	14 22
274		There is an urgent need for unequivocal guidance to be given to trusts and their legal advisers and those handling disclosure of information to coroners, patients and families, as to the priority to be given to openness over any perceived material interest.	2
275	Independent medical examiners	It is of considerable importance that independent medical examiners are independent of the organisation whose patients' deaths are being scrutinised.	14
276		Sufficient numbers of independent medical examiners need to be appointed and resourced to ensure that they can give proper attention to the workload.	14
277	Death certification	National guidance should set out standard methodologies for approaching the certification of the cause of death to ensure, so far as possible, that similar approaches are universal.	14
278		It should be a routine part of an independent medical examiners's role to seek out and consider any serious untoward incidents or adverse incident reports relating to the deceased, to ensure that all circumstances are taken into account whether or not referred to in the medical records.	14
279		So far as is practicable, the responsibility for certifying the cause of death should be undertaken and fulfilled by the consultant, or another senior and fully qualified clinician in charge of a patient's case or treatment.	14
280	Appropriate and sensitive contact with bereaved families	Both the bereaved family and the certifying doctor should be asked whether they have any concerns about the death or the circumstances surrounding it, and guidance should be given to hospital staff encouraging them to raise any concerns they may have with the independent medical examiner.	14
281		It is important that independent medical examiners and any others having to approach families for this purpose have careful training in how to undertake this sensitive task in a manner least likely to cause additional and unnecessary distress.	14
282	Information for, and from, inquests	Coroners should send copies of relevant Rule 43 reports to the Care Quality Commission.	14
283		Guidance should be developed for coroners' offices about whom to approach in gathering information about whether to hold an inquest into the death of a patient. This should include contact with the patient's family.	14
284	Appointment of assistant deputy coroners	The Lord Chancellor should issue guidance as to the criteria to be adopted in the appointment of assistant deputy coroners.	14
285	Appointment of assistant deputy coroners	The Chief Coroner should issue guidance on how to avoid the appearance of bias when assistant deputy coroners are associated with a party in a case.	14

Rec. no.	Theme	Recommendation	Chapter
	Department of Health leadership		
286	Impact assessments before structural change	Impact and risk assessments should be made public, and debated publicly, before a proposal for any major structural change to the healthcare system is accepted. Such assessments should cover at least the following issues: • What is the precise issue or concern in respect of which change is necessary? • Can the policy objective identified be achieved by modifications within the existing structure? • How are the successful aspects of the existing system to be incorporated and continued in the new system? • How are the existing skills which are relevant to the new system to be transferred to it? • How is the existing corporate and individual knowledge base to be preserved, transferred and exploited? • How is flexibility to meet new circumstances and to respond to experience built into the new system to avoid the need for further structural change? • How are necessary functions to be performed effectively during any transitional period? • What are the respective risks and benefits to service users and the public and, in particular, are there any risks to safety or welfare?	19
287		The Department of Health should together with healthcare systems regulators take the lead in developing through obtaining consensus between the public and healthcare professionals, a coherent, and easily accessible structure for the development and implementation of values, fundamental, enhanced and developmental standards as recommended in this report.	19
289	Clinical input	The Department of Health should ensure that there is senior clinical involvement in all policy decisions which may impact on patient safety and well-being.	19
289	Experience on the front line	Department of Health officials need to connect more to the NHS by visits, and most importantly by personal contact with those who have suffered poor experiences. The Department of Health could also be assisted in its work by involving patient/service user representatives through some form of consultative forum within the Department.	19
290		The Department of Health should promote a shared positive culture by setting an example in its statements by being open about deficiencies, ensuring those harmed have a remedy, and making information publicly available about performance at the most detailed level possible.	19

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ISBN 978-0-10-298147-6

9 780102 981476